

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

Appellants: Bianchi, <i>et al.</i>	)	
	)	
Serial No.: 09/782,594	)	Electronically Filed on
	)	
Filed: February 12, 2001	)	
	)	Date: September 30, 2008
For: "Assembled Implant"	)	
	)	
Group Art Unit: 3774	)	
	)	
Examiner: Paul B Prebille	)	
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APPELLANTS' BRIEF ON APPEAL UNDER 37 CFR § 1.192  
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Mail Stop Appeal Brief-Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sarah A. Kofflin  
Registration No. 60,218  
Attorney for Appellants  
500 West Madison Street  
34th Floor  
Chicago, Illinois 60661  
(312) 775-8000

Of Counsel:  
MCANDREWS, HELD & MALLOY, LTD.  
500 West Madison Street  
34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8000

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CLAIMS APPENDIX

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Dear Sir:

In response to the Official Action of April 4, 2008, rejecting all pending claims (claims 26-30), and the Notice of Appeal filed on July 1, 2008, for which a Brief on Appeal under 37 C.F.R. § 1.192 is due on October 1, 2008 with a Petition for a One-Month Extension, the Appellants hereby file this Brief on Appeal, appealing the bases for final rejection of all the pending claims (*i.e.*, claims 26-30).

The Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the pending rejections of claims 26-30 of the present application.

## **I. REAL PARTY IN INTEREST**

The real party in interest in the above-identified application is RTI Biologics, Inc., a Delaware corporation, having a principal place of business at 11621 Research Circle, Alachua FL 32615.

## **II. RELATED APPEALS AND INTERFERENCES**

There is a pending appeal regarding U.S. Patent Application Serial No. 10/387,322, which is a continuation-in-part of the instant application, and thus may directly affect, be affected by, or have a bearing on the Board of Patent Appeals and Interferences' decision in the pending appeal. The Brief on Appeal with respect to U.S. Patent Application Serial No. 10/387,322 was filed on November 22, 2006. A Notice of Non-Compliant Brief was sent on January 5, 2007, and a response including an Amended Brief on Appeal was filed on February 5, 2007. A second Notice of Non-Compliant Brief was sent on June 5, 2007, and a response was filed on July 2, 2007. The Examiner's answer was sent on October 19, 2007.

There has been no decision rendered by the Board in the pending appeal regarding U.S. Patent Application Serial No. 10/387,322. Consequently, there are no materials attached in the Related Proceedings Appendix.

There is also a pending appeal regarding U.S. Patent Application Serial No. 09/905,683, which contains related subject matter to the current application, and thus may directly affect, be affected by, or have a bearing on the Board of Patent Appeals and Interferences' decision in the pending appeal. The Brief on Appeal with respect to U.S. Patent Application Serial No. 09/905,683 was filed on March 12, 2007. A Notice of Non-Compliant Brief was sent on May 11, 2007, and a response was filed on June 11, 2007. A second Notice of Non-Compliant Brief was sent on September 13, 2007, and a response including an Amended Brief on Appeal was filed on October 15, 2007. A third Notice of Non-Compliant Brief was sent on November 6, 2007, and a response was filed on December 6, 2007. The Examiner's answer was sent on March 11, 2008. A reply brief was filed on May 12, 2008.

There has been no decision rendered by the Board in the pending appeal regarding U.S. Patent Application Serial No. 09/905,683. Consequently, there are no materials attached in the Related Proceedings Appendix.

### **III. STATUS OF THE CLAIMS**

The present application was filed on February 12, 2001 with claims numbered 1-47 and 49-61.<sup>1</sup> A Notice to File Missing Parts of Nonprovisional Application was mailed on March 19, 2001,<sup>2</sup> to which a Response was filed on May 21, 2001.<sup>3</sup> Applicants submitted new formal drawing on July 23, 2001.<sup>4</sup> A Preliminary Amendment was filed on July 25, 2001, in which claims 1-25 were canceled.<sup>5</sup>

A restriction requirement under 35 U.S.C. §121 was mailed on July 31, 2003.<sup>6</sup> Appellants filed a Response to the restriction requirement on August 22, 2003 electing the species of claims 26-42 and 44-61.<sup>7</sup> Claim 43 was withdrawn from consideration as being drawn to non-elected inventions or species.

In a non-final Office Action mailed November 4, 2003, the Office Action noted that there was no claim 48 in the originally filed claims and renumbered claims 49-61 as 48-60.<sup>8</sup> In the November 4, 2003 Office Action claims 38, 41, 42 and 53-55 were rejected under 35 U.S.C. §112

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<sup>1</sup> Exhibit 1, Evidence Appendix.

<sup>2</sup> Exhibit 2, Evidence Appendix.

<sup>3</sup> Exhibit 3, Evidence Appendix

<sup>4</sup> Exhibit 4, Evidence Appendix.

<sup>5</sup> Exhibit 5, at p. 1, Evidence Appendix

<sup>6</sup> Exhibit 6, Evidence Appendix.

<sup>7</sup> Exhibit 7, at pp. 1, Evidence Appendix

<sup>8</sup> Exhibit 8, at p. 2, Evidence Appendix.

and claims 26-42, 44 and 46-60 were rejected under 35 U.S.C. §102(e).<sup>9</sup> In an Amendment and Response dated May 4, 2004, claims 26-34 were amended and claims 35-60 were cancelled.<sup>10</sup>

A final Office Action was then mailed on July 23, 2004, in which claims 26-34 were rejected under 35 U.S.C. §102.<sup>11</sup> Applicants submitted an Amendment and Response dated November 19, 2004, attempting to amend claim 32.<sup>12</sup> However, the Examiner refused to enter the amendments in an Advisory Action dated December 12, 2004.<sup>13</sup> On December 9, 2004 Applicants submitted substitute drawings requested by the Examiner.<sup>14</sup> The Examiner once again refused to enter the amendments in an Advisory Action dated January 4, 2005.<sup>15</sup> On January 20, 2005, a Request for Continued Examination was filed together with a request for entry of the amendments and arguments that the Examiner previously refused to enter (the Request for Continued Examination refers to Applicants' Request for Reconsideration filed October 29, 2004, but examination of further prosecution indicates this is merely a typographical error and was meant to be November 19, 2004).<sup>16</sup>

A non-final rejection was mailed on March 24, 2005, in which claims 26-34 were rejected for provisional double patenting, claim 29 was objected to, claim 27 was rejected under 35 U.S.C. §112 second paragraph, claims 26-31 and 33-34 were rejected under 35 U.S.C. §102 and claim 32 was rejected under 35 U.S.C. §103(a).<sup>17</sup> In an Amendment and Response dated July 15, 2005, claims 26-29 and 31-34 were amended and new claims 61-62 were added.<sup>18</sup>

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<sup>9</sup> Id. at pp. 4-6

<sup>10</sup> Exhibit 9, at pp. 3-5, Evidence Appendix

<sup>11</sup> Exhibit 10, at pp. 3-4, Evidence Appendix.

<sup>12</sup> Exhibit 11, at pp. 2-3 Evidence Appendix.

<sup>13</sup> Exhibit 12, Evidence Appendix.

<sup>14</sup> Exhibit 13, Evidence Appendix.

<sup>15</sup> Exhibit 14, Evidence Appendix.

<sup>16</sup> Exhibit 15, Evidence Appendix.

<sup>17</sup> Exhibit 16, at pp. 2-6, Evidence Appendix.

<sup>18</sup> Exhibit 17, at pp. 2-4, Evidence Appendix

A final Office Action was then mailed on September 27, 2005, in which claims 26-34 and 60-61 were rejected for provisional double patenting, claims 26-34 were rejected under 35 U.S.C. §102(b) and claims 26, 27, 31-34 and 61-62 were rejected under 35 U.S.C. §103(a).<sup>19</sup> On November 21, 2005, a second Request for Continued Examination was filed together with amendments to claims 26-28 and 31-34 and arguments requesting reconsideration (claims 61 and 62 are listed as new in the listing of the claims but examination of the prosecution history indicates that this was in error).<sup>20</sup>

A non-final rejection was mailed on February 27, 2006, in which claims 33, 61 and 62 were objected to, claims 26-34 and 60-61 were rejected for provisional double patenting, claims 26-34 were rejected under 35 U.S.C. §102(b) and claims 26-34 and 61-62 were rejected under 35 U.S.C. §103(a).<sup>21</sup> In an Amendment and Response dated August 25, 2006, claims 26-34 were amended.<sup>22</sup>

A final Office Action was then mailed on October 25, 2006, in which claim 26 and 28 were objected to, claims 26 and 33 were rejected for provisional double patenting, claims 26-27 and 31-34 were rejected under 35 U.S.C. §102(b) and claims 26-34 and 61-62 were rejected under 35 U.S.C. §103(a).<sup>23</sup> On February 26, 2007, a third Request for Continued Examination was filed together with an Amendment and Response.<sup>24</sup> The Amendment and Response amended claims 26-30 and 34.<sup>25</sup>

A non-final rejection was mailed on May 3, 2007, in which claims 26 and 33 were rejected for provisional double patenting, claims 31-34 were rejected under 35 U.S.C. §102(b) and claim 26-34 and 61-62 were rejected under 35 U.S.C. §103(a).<sup>26</sup> In an Amendment and Response dated

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<sup>19</sup> Exhibit 18, at pp. 2-4, Evidence Appendix.

<sup>20</sup> Exhibit 19, Evidence Appendix.

<sup>21</sup> Exhibit 20, at pp. 2-6, Evidence Appendix.

<sup>22</sup> Exhibit 21, at pp. 2-4, Evidence Appendix.

<sup>23</sup> Exhibit 22, at pp. 2-6, Evidence Appendix.

<sup>24</sup> Exhibit 23, Evidence Appendix.

<sup>25</sup> Id. at pp. 2-4.

<sup>26</sup> Exhibit 24, at pp. 2-6, Evidence Appendix.

November 5, 2007, claims 31-34, 61 and 62 were cancelled.<sup>27</sup> Two Notices of Non-Compliant Amendment were received on January 15, 2008 and March 3, 2008.<sup>28</sup> Applicants responded on January 25, 2008 and March 24, 2008 respectively.<sup>29</sup>

A final Office Action was then mailed on April 4, 2008, in which claims 26-30 were rejected under 35 U.S.C. §103(a).<sup>30</sup> In accordance with 35 U.S.C. §134, each of the pending claims having been rejected more than twice, a Notice of Appeal was then filed on July 1, 2008.<sup>31</sup>

In the present application, claims 26-30 are pending and have been rejected more than twice. All presented amendments to these claims have been entered. Claims 26-30 as currently pending are presented for consideration on appeal. The text of pending claims 26-30 is attached in the Claims Appendix filed herewith.

#### **IV. STATUS OF THE AMENDMENTS**

No amendments to the pending claims were submitted after the final Office Action mailed April 4, 2008.

#### **V. SUMMARY OF THE CLAIMED SUBJECT MATTER**

Pending independent claim 26 is directed to “an assembled bone graft, said assembled bone graft assembled outside the body and suitable for implantation into a human patient, said assembled bone graft comprising: a plurality of machined allograft bone portions layered to form a graft unit, and pins comprising cortical bone traversing said graft unit for holding said graft unit together as an assembled bone graft, wherein said assembled bone graft does not include an adhesive.”<sup>32</sup>

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<sup>27</sup> Exhibit 25, at pp. 2-3, Evidence Appendix

<sup>28</sup> Exhibits 26 and 27, Evidence Appendix.

<sup>29</sup> Exhibits 28 and 29, Evidence Appendix.

<sup>30</sup> Exhibit 30, at pp. 2-4, Evidence Appendix.

<sup>31</sup> Exhibit 31, Evidence Appendix.

<sup>32</sup> Claim 26, Claims Appendix.

Support for independent claim 26 can be found throughout the specification of the application as filed. For example, the Field of the Invention section of the application as filed states, “[t]his invention relates to implants and methods for their preparation wherein components of the implant are assembled from constituent pieces to produce a complete implant.”<sup>33</sup> Similarly, the Summary of the Invention states “[t]his invention provides a method for manufacture of autograft, allograft and xenograft implants which comprises assembling such implants from smaller pieces of graft materials to form a larger graft implant product.”<sup>34</sup> Accordingly, the present application supports assembled bone grafts made from a plurality of allograft bone portions.

At the beginning of the Detailed Description, the specification states “[t]he present invention provides methods for manufacture of autograft, allograft and xenograft implants by assembling such implants from smaller pieces of graft materials to form a larger graft implant product.”<sup>35</sup> In one exemplary description of the bone graft of the present application, the specification states:

Thus, for example, in an assembled bone dowel implant according to this invention, the assembled bone dowel comprises segments of cortical bone pinned to each other by means of cortical bone pins.<sup>36</sup>

In another exemplary description of the bone graft of the present application, the specification states:

It will be appreciated that variously shaped wafers, blocks, rings, washer-shaped bone pieces and the like may be affixed to each other in any secure and biologically acceptable manner. Preferably, the assembled pieces of bone are affixed to each other by means of pins, screws, rods, interference fit, threaded fits, key-way fit, and the like made from cortical bone. These fixation pieces are machined in a CNC lathe or the like to appropriate dimensions and are then threaded into mating holes tapped in the pieces to be assembled, or are pressed into drilled holes through adjacent pieces to be assembled by a pneumatic press or

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<sup>33</sup> Exhibit 1, at p. 1, lns 15-16, Evidence Appendix.

<sup>34</sup> Id. at p. 3, lns 3-5.

<sup>35</sup> Id. at p. 4, lns 19-22.

<sup>36</sup> Id. at p. 5, lns 8-1. (Emphasis added).

the like. In this fashion, very strong and tightly fitted pieces of implant material may be joined and implanted.<sup>37</sup>

In another exemplary description of the bone graft of the present application, the specification states:

In view of the present disclosure, it will be appreciated that this invention provides a wide variety of assembled implants and implant parts: dowel shaped implants comprising assembled dowel segments, between about two to about ten segments, pinned together by one or more cortical bone pins. The assembled segments may closely abut each other or may be spread apart from each other. Such implants may be prepared by harvesting disks of cortical bone, drilling and optionally tapping holes therein, and inserting shafts of cortical pins therethrough, or therein, optionally by threading portions thereof for torquing into optionally tapped holes.<sup>38</sup>

The flow chart illustrated in Figure 1,<sup>39</sup> as well as the description thereof in the specification,<sup>40</sup> provide additional support for claim 26.

From this figure, it will be appreciated that a central concept relevant to the present invention is the ability to machine smaller parts of tissue, specifically bone tissue, such as cortical bone, cancellous bone, cortical-cancellous bone, portions of which may be demineralized (see, for example, U.S. Pat. No. 6,090,998, hereby incorporated herein by reference for this purpose), and assemble these portions of tissue using, preferably, cortical bone pins. The assembled tissue pieces may be machined prior to assembly, and then, upon assembly, a complete implant is ready for implantation.<sup>41</sup>

Similarly, Figure 2<sup>42</sup> and the description thereof<sup>43</sup> provide support for claim 26. With regard to Figure 2, the specification states:

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<sup>37</sup> Id. at p. 5, lns 15-23. (Emphasis added).

<sup>38</sup> Id. at p. 7, lns 4-11. (Emphasis added).

<sup>39</sup> Id. at p. 27.

<sup>40</sup> Id. at p. 9, ln. 1 through p. 10, ln. 11.

<sup>41</sup> Id. at p. 9, lns 8-15. (Emphasis added).

<sup>42</sup> Id. at p. 28.

<sup>43</sup> Id. at p. 10, lns 13-30.

With reference to FIG. 2, there is shown two machined bone pieces, T and Z each of which bear external threading X and holes Y into which pins A are inserted to form the assembled graft 200. As can be seen, the assembled graft 200 comprises a void, 201 into which osteogenic material may be inserted prior to or after implantation. The pins Y may be metal pins, but preferably are pins machined from cortical bone. This enables the entire implant to remodel into autogenous tissue over time, such as vertebral bone, when the implant 200 is inserted into the intervertebral space. The graft 201 is also shown with a groove, 202 in which a driver may be inserted to provide rotational torque for insertion of the implant. An instrument attachment hole, 203, is also provided, to ensure that the implant remains securely on the head of the driver means in the process of surgical implantation. Naturally, those skilled in the art will appreciate that the segments Z and T may be brought into close abutment with each other, thereby eliminating the space 201. In that event, the length of the pins A would be modified to prevent unnecessary protrusion, although in some applications, protrusion may be useful when driving the implant 200 into place.

Additional support can be found, for example, at page 5, lines 23-24 (“assembled pieces may first be machined to desired dimensions and shapes”); at page 6, lines 3-6 (“insertion therein of cortical bone pins”); at page 8, lines 19-20 (“an assembled allograft or xenograft tissue implant”); at originally filed claims 1-3, 11, 28-37 (“does not comprise an adhesive”), 41, 42, 44 ; and at the Abstract at p. 16, lines 3-5 (“autograft, allograft and xenograft implants which comprise assembling such implants from smaller pieces of graft materials to form a larger graft implant product”).<sup>44</sup>

Pending independent claim 27 is directed to “an assembled bone graft suitable for implantation in a human patient comprising: two distinct bone portions of cortical bone, and pins comprising cortical bone, wherein said two distinct bone portions are machined allograft bone portions processed to be suitable for implantation in a human patient, said pins are of appropriate diameter and press fitted into machined holes in said two bone portions to hold together said two bone portions to form an assembled bone graft suitable for implantation in humans.”<sup>45</sup>

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<sup>44</sup> Exhibit 1, Evidence Appendix.

<sup>45</sup> Claim 27, Claims Appendix.

Support for independent claim 27 can be found throughout the specification of the application as filed, for example, at page 1, lines 15-16 (“invention relates to implants and methods for their preparation wherein components of the implant are assembled from constituent pieces to produce a complete implant”); at page 3, lines 3-5 (“invention provides a method for manufacture of autograft, allograft and xenograft implants which comprises assembling such implants from smaller pieces of graft materials to form a larger graft implant product”); page 4, lines 19-22 (“invention provides methods for manufacture of autograft, allograft and xenograft implants by assembling such implants from smaller pieces of graft materials to form a larger graft implant product”); at page 5, lines 8-1 (“in an assembled bone dowel implant according to this invention, the assembled bone dowel comprises segments of cortical bone pinned to each other by means of cortical bone pins”); at page 5, lines 15-23 (“fixation pieces are machined in a CNC lathe or the like to appropriate dimensions and are then threaded into mating holes tapped in the pieces to be assembled, or are pressed into drilled holes through adjacent pieces to be assembled by a pneumatic press or the like. In this fashion, very strong and tightly fitted pieces of implant material may be joined and implanted”); at page 5, lines 23-24 (“assembled pieces may first be machined to desired dimensions and shapes”); at page 6, lines 3-6 (“insertion therein of cortical bone pins”); at page 7, lines 4-11 (“prepared by harvesting disks of cortical bone, drilling and optionally tapping holes therein, and inserting shafts of cortical pins therethrough, or therein, optionally by threading portions thereof for torquing into optionally tapped holes”); at page 8, lines 19-20 (“an assembled allograft or xenograft tissue implant”); at Fig. 1 and the associated description at page 9, line 1 through page 10, line 11; at Fig. 2 and the associated description at page 10, lines 13-30; at originally filed claims 1-3, 11, 28-37 (“does not comprise an adhesive”), 41, 42, 44 ; and at the Abstract at p. 16, lines 3-5 (“autograft, allograft and xenograft implants which comprise assembling such implants from smaller pieces of graft materials to form a larger graft implant product”).<sup>46</sup>

Pending independent claim 28 is directed to “an assembled bone graft suitable for implantation in a human patient comprising two or more distinct bone portions of machined allograft bone and pins comprising cortical bone, said two or more distinct bone portions having

<sup>46</sup> Exhibit 1, Evidence Appendix.

holes therein for receiving said pins, said pins keeping said two or more distinct bone portions aligned and connected to form said assembled bone graft free of an adhesive and suitable for implantation in a human.”<sup>47</sup>

Support for independent claim 28 can be found throughout the specification of the application as filed, for example, at page 1, lines 15-16 (“invention relates to implants and methods for their preparation wherein components of the implant are assembled from constituent pieces to produce a complete implant”); at page 3, lines 3-5 (“invention provides a method for manufacture of autograft, allograft and xenograft implants which comprises assembling such implants from smaller pieces of graft materials to form a larger graft implant product”); page 4, lines 19-22 (“invention provides methods for manufacture of autograft, allograft and xenograft implants by assembling such implants from smaller pieces of graft materials to form a larger graft implant product”); at page 5, lines 8-1 (“in an assembled bone dowel implant according to this invention, the assembled bone dowel comprises segments of cortical bone pinned to each other by means of cortical bone pins”); at page 5, lines 15-23 (“fixation pieces are machined in a CNC lathe or the like to appropriate dimensions and are then threaded into mating holes tapped in the pieces to be assembled, or are pressed into drilled holes through adjacent pieces to be assembled by a pneumatic press or the like. In this fashion, very strong and tightly fitted pieces of implant material may be joined and implanted”); at page 5, lines 23-24 (“assembled pieces may first be machined to desired dimensions and shapes”); at page 6, lines 3-6 (“insertion therein of cortical bone pins”); at page 7, lines 4-11 (“prepared by harvesting disks of cortical bone, drilling and optionally tapping holes therein, and inserting shafts of cortical pins therethrough, or therein, optionally by threading portions thereof for torquing into optionally tapped holes”); at page 8, lines 19-20 (“an assembled allograft or xenograft tissue implant”); at Fig. 1 and the associated description at page 9, line 1 through page 10, line 11; at Fig. 2 and the associated description at page 10, lines 13-30; at originally filed claims 1-3, 11, 28-37 (“does not comprise an adhesive”), 41, 42, 44 ; and at the Abstract at p. 16, lines 3-5 (“autograft, allograft and

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<sup>47</sup> Claim 28, Claims Appendix.

xenograft implants which comprise assembling such implants from smaller pieces of graft materials to form a larger graft implant product”).<sup>48</sup>

Pending claim 29 depends from claim 28 and is directed to the “assembled bone graft of claim 28 where there are two distinct bone portions of machined allograft bone.”<sup>49</sup> Support for claim 29 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 28. Specific support for the two distinct portions of machined allograft bone can be found throughout the specification of the application as filed, including at p. 4, lines 19-22 (“[t]he present invention provides methods for manufacture of ...allograft...implants by assembling such implants from smaller pieces of graft material to form a larger graft implant product”) and at p. 5, lines 23-25 (“assembled pieces may be machined”).<sup>50</sup>

Pending claim 30 depends from claim 28 and is directed to the “assembled bone graft of claim 28, wherein said two or more distinct bone portions are selected from the group consisting of: cortical bone and cancellous bone.”<sup>51</sup> Support for claim 30 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 28. Specific support for the two or more distinct bone portions comprising cortical or cancellous bone can be found throughout the specification of the application as filed, including at p. 6, lines 5-7 (“an assembled implant is prepared comprising different segments of cortical bone, cancellous bone or both”) and at p. 9, lines 8-13 (“central concept relevant to the present invention is the ability to machine smaller parts of tissue, specifically bone tissue, such as cortical bone, cancellous bone, cortical-cancellous bone”).<sup>52</sup>

In view of the foregoing discussion, the invention as claimed is fully supported by the application as originally filed.

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

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<sup>48</sup> Exhibit 1, Evidence Appendix.

<sup>49</sup> Claim 29, Claims Appendix.

<sup>50</sup> Exhibit 1, Evidence Appendix.

<sup>51</sup> Claim 30, Claims Appendix.

<sup>52</sup> Exhibit 1, Evidence Appendix.

Whether the Office Action erred in rejecting claims 26-30 under 35 U.S.C. §103(a) over European Patent Application No. 0517030 (hereinafter the “Siebels” reference)<sup>53</sup> in view of U.S. Pat. No. 5,989,289 (hereinafter the “Coates” reference)<sup>54</sup> where the prior art provides no basis to combine the teachings of these references, nor a reasonable expectation of success with respect to making such a combination of the reference teachings, and where the cited references do not disclose each and every element of the rejected claims.

## **VII. ARGUMENT**

The Office Action erred in rejecting claims 26-30 under 35 U.S.C. §103(a) over the Siebels<sup>55</sup> reference in view of the Coates<sup>56</sup> reference because the prior art provides no basis to combine the reference teachings, nor a reasonable expectation of success with respect to making such a combination of the reference teachings, and the cited references do not disclose each and every element of the rejected claims.

The Office Action made several errors in maintaining the pending obviousness rejection over the Siebels reference in light of the Coates reference. For example, the Office Action has relied upon conclusory statements rather than establishing a reason to combine the cited references. Additionally, the obviousness rejection fails to consider the prior art references as a whole, including teachings within them that teach away from the combination that Office Action relies upon. Further, the Office Action has not established any basis for concluding that one of ordinary skill in the art would have a reasonable expectation of success in combining the Coates reference with the Siebels reference.

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<sup>53</sup> Exhibit 32, Evidence Appendix. (English translation attached.)

<sup>54</sup> Exhibit 33, Evidence Appendix.

<sup>55</sup> Exhibit 32, Evidence Appendix. (English translation attached.)

<sup>56</sup> Exhibit 33, Evidence Appendix.

**A. Conclusory Statements Are Insufficient to Establish A Basis To Combine The Siebels Reference With The Coates Reference To Arrive At The Subject Matter Of Claims 26-30**

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”<sup>57</sup> This is necessary to prevent the use of hindsight based upon the teachings of the Appellants’ invention.<sup>58</sup>

In the final Office Action, dated April 4, 2008, the Siebels reference was cited as disclosing “an assembled bone implant made by assembling separate bone pieces together to form an implant by aligning bores (sic) of adjacent pieces.”<sup>59</sup> Siebels was further cited as introducing “pins into the aligned bones to hold the implant pieces together.”<sup>60</sup> The final Office Action, however, admitted that “Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber reinforced plastics (see page 3, last lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6).”<sup>61</sup> The final Office Action then asserted that “Coates, however, teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo.”<sup>62</sup> The final Office Action then jumps to a conclusion of obviousness, stating that “[i]t would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons that Coates teaches doing the same.”<sup>63</sup> The final Office

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<sup>57</sup> In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329 (Fed. Cir. 2006); See also Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1291, 80 U.S.P.Q.2d 1001 (Fed. Cir. 2006).

<sup>58</sup> See MPEP at § 2142.

<sup>59</sup> Exhibit 30, at p. 2, Evidence Appendix.

<sup>60</sup> Exhibit 30, at p. 2, Evidence Appendix.

<sup>61</sup> Exhibit 30, at p. 3, Evidence Appendix.

<sup>62</sup> Exhibit 30, at p. 3, Evidence Appendix.

<sup>63</sup> Exhibit 30, at p. 3, Evidence Appendix. See also Exhibit 30, at p. 5, Evidence Appendix (“there would be nothing stopping an ordinary artisan from applying the teaching of Coates to that of Siebels to arrive at the claimed invention”).

Action thus oversimplifies both the Siebels reference and the Coates reference, and then simply makes a conclusory allegation of obviousness without articulated reasoning and/or rational underpinnings to support the legal conclusion of obviousness. This results in an erroneous final rejection under 35 U.S.C. §103(a).

With respect to the present application, no basis for combining the cited references has been provided. Instead, improper hindsight reasoning has been applied by finding the individual elements of the Appellants' claims in separate references and then simply concluding that it would have been obvious to one of ordinary skill to combine those references. The final Office Action reasons that "there would be nothing stopping an ordinary artisan from applying the teaching of Coates to that of Siebels to arrive at the claimed invention."<sup>64</sup> However, a generalized conclusion that there was "nothing stopping" a combination of references is not sufficient to sustain a rejection under 35 U.S.C. §103(a). Rather, an obviousness rejection must include "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."<sup>65</sup> Clinging to an unproven possibility that the references could be combined to achieve the claimed invention with a reasonable expectation of success is not sufficient to establish obviousness.

**B. The Cited References, Considered As A Whole, Do Not Provide A Basis To Combine The Siebels Reference With The Coates Reference To Arrive At The Subject Matter Of Claims 26-30**

When prior art references are combined, the references must be considered in their entirety, "i.e., as a whole, including portions that would lead away from the claimed invention."<sup>66</sup> Appellants respectfully submit that when the substance and teachings of the Siebels reference and the Coates reference are properly considered, it is clear that one of ordinary skill in the art

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<sup>64</sup> Exhibit 30, at p. 5, Evidence Appendix.

<sup>65</sup> In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, (Federal Circuit 2006); See also Alza Corp. v. Mylan Labs, Inc., 464 F.3d 1286, 1291, 80 U.S.P.Q.2d 1001 (Federal Circuit 2006).

<sup>66</sup> MPEP at § 2141.02. (Emphasis added.)

would not combine the two references by replacing the materials used in Siebels with the cortical bone used in the implants of Coates.

The Siebels reference describes the basis of the invention described therein in the following manner:

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.<sup>67</sup>

Ease of manufacturing and ease of implantation are thus aspects of the basis for the Siebels invention, and serve as the solutions for the nature of the problem addressed by Siebels. To achieve the aspect of "ease" of manufacturing, Siebels relies upon cutting disks out of a "prefabricated solid or hollow strand."<sup>68</sup>

The only materials actually described in the Siebels reference from which the disks and/or anchoring pins described therein can be made are "fiber reinforced plastic"<sup>69</sup> and "carbon-fiber reinforced plastic."<sup>70</sup> Specifically, on page 3, the Siebels reference states, "The disk-shaped implant is preferably made of fiber-reinforced plastic," and on page 6, the Siebels reference states that "the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means - according to the design of the implant - can consist of the same, or another material."<sup>71</sup> The Siebels reference, however, does not describe any other material from which its implants or anchoring pins can be made.

With respect to the anchoring pins disclosed in the Siebels reference, there is no discussion, aside from the one reference to carbon-fiber reinforced plastic on page 6, of suitable materials from which they can be made. Nor is there any discussion of the parameters or factors

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<sup>67</sup> Exhibit 32, at p. 2, English translation, Evidence Appendix. (Emphasis added)

<sup>68</sup> Id. at p. 3.

<sup>69</sup> Id.

<sup>70</sup> Id. at p. 6.

<sup>71</sup> Id. at pp. 3, 6.

that should be considered when choosing the material from which to make the anchoring pins. Thus, there is no teaching within Siebels to guide one of ordinary skill in the art in choosing any material for the anchoring pins other than carbon-fiber reinforced plastic.

With respect to the disks used for the implants described in the Siebels reference, the Siebels reference contains the following discussion:

From the standpoint of manufacturing engineering, annular disks or solid disks can easily be manufactured of any biologically compatible material because they are not bound to a particular shaping. The shape can even partially be matched to the manufacturing method. Manufacturing methods, which are adequate for the series-manufacturing are winding or palling of bonded-fiber tubes, out of which the disks are sawn off, cut off, or separated, either as individual element or as elements for the disk packings [packages], described above.<sup>72</sup>

This paragraph, as well as the specification when read as a whole, shows that the general statement regarding "any biologically compatible material" is actually limited in scope and does not extend to disks made from cortical bone such as those described and claimed in the present application. The manufacturing methods by which the implants of Siebels can "easily be manufactured" in accordance with the "basis of the [proposed] invention"<sup>73</sup> make it evident that the only suitable materials are the plastics described therein.

With respect to the structural elements and physical characteristics of the implants disclosed in Siebels, the Siebels reference describes that:

The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having a rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.<sup>74</sup>

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<sup>72</sup> Id. at p. 10.

<sup>73</sup> Id. at p. 2.

<sup>74</sup> Id. at pp. 3-4. (Emphasis added).

As another example, the Siebels reference particularly describes its stacked embodiments with reference to the manufacturing techniques:

In accordance with an embodiment of the invention, the disks have aligned boreholes, into which anchoring pins or studs can be inserted. In that embodiment, the disks are radially connected to one another, and also in such a way that they resist the torsional stress [i.e. possess torsional strength], and cannot rotate. Moreover, from a manufacturing engineering standpoint, the manufacturing of the disks is very easy.<sup>75</sup>

The Siebels reference then proceeds to describe the easy manufacturing techniques in the following manner:

Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ["washers"] can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.

Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages [packings] can be designed.<sup>76</sup>

The structure and shape of the disks described by Siebels are thus dictated by the braided or wound strands from which they are cut, and even the strength and rigidity of the disks is a result of the oriented fibers that result from the manufacturing techniques. The manufacturing methods taught in the Siebels reference that achieve the described advantages may be suitable for use with the plastics described in Siebels, but most could not be performed on cortical bone (i.e. braiding, winding, etc.), and there is no teaching within the Siebels reference regarding whether the

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<sup>75</sup> Id. at p. 5. (Emphasis added).

<sup>76</sup> Id. at pp. 6-7. (Emphasis added).

implants disclosed therein would possess the necessary physical properties (e.g., strength, rigidity, resistance to torsional stress) if applied to implants made from bone, such as those disclosed in the Coates reference. There is no basis in the Siebels reference for concluding that the disclosed manufacturing techniques could be altered or disregarded in making the disks taught therein.

The Siebels reference, when read as a whole, is directed to providing implants and implant components that can be easily manufactured. The Siebels reference thus teaches away from the use of materials or manufacturing techniques that do not provide the benefit of easy manufacturing as described within the Siebels reference. There is no teaching or suggestion in Siebels that the manufacturing techniques could be altered or disregarded in making the disks taught therein.

The pending rejection under 35 U.S.C. §103(a) improperly disregards the teachings of Siebels with respect to manufacturing. For example, the final Office Action admits that “Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6).”<sup>77</sup> The Office Action then simply imposes a substitution in implant material without taking into consideration the Siebels requirement of easy manufacturing.<sup>78</sup> The Office Action disregards the manufacturing considerations of Siebels in forming the pending obviousness rejection when it incorrectly asserts that “Siebels is referring more to the assembly and sizing of the device just prior to surgery rather than the overall process of making.”<sup>79</sup>

Such a disregard to the teachings of a prior art reference is improper. A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant, such as where the prior art

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<sup>77</sup> Exhibit 30, at p. 3, Evidence Appendix.

<sup>78</sup> Id.

<sup>79</sup> Id. at pp. 4-5.

criticizes, discredits, or otherwise discourages the solution claimed.<sup>80</sup> Furthermore, “[a] prior art reference that ‘teaches away’ from the claimed invention is a significant factor to be considered in determining obviousness.”<sup>81</sup>

In reading the Siebels reference, one of ordinary skill would be led towards the ease of manufacturing obtained by using the plastics and manufacturing methods described in Siebels, as well as the desirable physical properties provided by such manufacturing methods and materials. One of ordinary skill in the art would therefore be led in a divergent direction from developing different manufacturing techniques to allow the use of bone as a manufacturing material for assembled implants having multiple pieces, and taking on the challenges and disadvantages of bone such as those described in the Coates reference. Thus, had the Office Action properly considered the Siebels reference as a whole, the Office Action would not have made and maintained the obviousness rejection of claims 26-30.

Since Siebels relies so heavily on the use of particular materials and manufacturing techniques to achieve its objectives, one would not expect that a completely different material could be substituted and still meet the same objectives. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”<sup>82</sup> One would not have expected that cortical bone could be used in place of the disks prepared from plastics (e.g. a multiple number of braided layers), or that the easy manufacturing techniques of Siebels would still be useful when utilizing bone as the implant material.

Additionally, the Coates reference, when considered as a whole, teaches away from using cortical bone in the implants of Siebels. As an initial matter, the implants disclosed in the Coates reference differ from the assembled implants claimed in the present application in several respects. As described in Coates, “[t]he spacer 110 includes an anterior wall 111 having

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<sup>80</sup> MPEP at §2145(X)(D)(1).

<sup>81</sup> *Id.*

<sup>82</sup> MPEP §2143.01

opposite ends 112, 113, a posterior wall 115 having opposite ends 116, 117 and two lateral walls 120, 121. Each of the lateral walls 120, 121 is connected between the opposite ends 112, 113, 116, 117 of the anterior 111 and posterior 115 walls to define a chamber 130. The walls are each composed of a bone composition, preferably cortical bone.”<sup>83</sup> In contrast to the claimed implants of the present application, the Coates reference does not describe assembled implants made from multiple pieces of cortical bone, nor does it describe connecting pieces using cortical bone pins.

Additionally, the Coates reference discusses some of the disadvantages and difficulties with respect to making implants from bone:

Both allograft and autograft present additional difficulties. Graft alone may not provide the stability required to withstand spinal loads....

Several attempts have been made to develop a bone graft substitute which avoids the disadvantages of metal implants and bone grafts while capturing advantages of both. In each case, developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been extremely difficult or impossible.<sup>84</sup>

This shows that it was considered “extremely difficult or impossible” to provide an implant that had the benefits of both bone and metal without their undesired properties. And, although the Coates reference goes on to describe its single piece bone implants as providing one solution to the difficulties associated with using bone implants, the Coates reference when read as a whole does not provide a basis for concluding that modifications to the structure of the Coates implants, such as those suggested by the Examiner to arrive at the subject matter of the currently pending claims, would result in a suitable implant.

The final Office Action disregards the teachings of the Coates reference in making the pending obviousness rejection. Instead of considering the teachings of the Coates reference, the final Office Action contends that Coates “teaches that it was known to make similar spinal implants [to those of Siebels] out of allograft or autograft cortical bone because of its superior properties in vivo.”<sup>85</sup> However, the Coates implants are single piece implants, not multiple

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<sup>83</sup> Exhibit 33, at Col. 5, ln 66 to Col. 6, ln 5, Evidence Appendix.

<sup>84</sup> Exhibit 33, at Col. 3, lns 17-40, Evidence Appendix. (Emphasis added).

<sup>85</sup> Exhibit 30, at p. 3, Evidence Appendix.

piece implants such as those disclosed in the Siebels reference. Further, Coates does not address or overcome the advantages associated with fiber reinforced plastic, so as to cause one skilled in the art to disregard the ease of construction and other stated advantages of the Siebels teachings.

In light of the disclosures of the Siebels reference and the Coates reference when read in their entirety, there simply is no basis to combine the Siebels reference and the Coates reference to arrive at implants or portions of implants made from multiple pieces of cortical bone connected by cortical bone pins as disclosed and claimed in the present application. Given the "extremely difficult or impossible"<sup>86</sup> setting of developing an implant from cortical bone as described in the Coates reference, one skilled in the art would not have been encouraged to substitute cortical bone of Coates for the "extraordinarily easy" to use braided or wound plastics of Siebels. Moreover, given the art recognized extreme difficulty or impossibility of developing a single piece implant from cortical bone as disclosed in Coates, one skilled in the art would have been even less likely to build an implant assembled from pieces of cortical bone held together with cortical bone pins.

As evidenced by the foregoing discussion, the pending rejection under 35 U.S.C. §103(a) is improperly based on the picking and choosing of isolated elements from the prior art references. The prior art teaches away from the modifications and changes relied upon in the Office Action. Additionally, the final Office Action is improperly based on hindsight reconstruction of the cited references, using the present invention as a template. The obviousness rejection over the Siebels reference in view of the Coates reference should therefore be withdrawn.

**C. No Basis For A Reasonable Expectation Of Success Has Been Established With Respect To Combining The Siebels Reference And The Coates Reference To Arrive At The Subject Matter Of Claims 26-30**

The MPEP requires that "there must be a reasonable expectation of success" that the prior art can be modified or combined as relied upon in the Office Action.<sup>87</sup> With respect to the present application, there has been no articulation of any basis for a reasonable expectation of

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<sup>86</sup> Exhibit 33, at Col. 3, ln 38-39, Evidence Appendix.

<sup>87</sup> MPEP §2143.02.

success in using cortical bone to manufacture implants and portions of implants made from multiple pieces held in place by cortical bone pins, as described and claimed by the Appellants. The failure to establish a reasonable expectation of success was legal error.

When addressing the issue of a reasonable expectation of success, the MPEP explains, “Obviousness does not require absolute predictability, however, at least some degree of predictability is required.”<sup>88</sup> The MPEP further states, “Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made.”<sup>89</sup> When the cited prior art references are viewed in this context, it becomes apparent that there is not a reasonable expectation of success with respect to modifying the multiple piece fiber-reinforced plastic implants of Siebels in view of the single piece cortical bone spacers disclosed in Coates. For example, given the difficulties with making bone grafts as described in the Coates reference, there would not have been a reasonable expectation of success that implants could be assembled from multiple pieces of cortical bone. Although the final Office Action in the present application states that “Coates at least implicitly can be said to overcome such difficulties,”<sup>90</sup> that assertion is incorrect because the Coates reference is directed to a single piece implant and does not address the utilization of multiple pieces.

Further, both the Coates reference and the Siebels reference discuss the need for implant strength, but neither addresses whether multiple cortical bone pieces connected by retention pins would provide such strength. For example, the Coates reference expresses the concern that “[g]raft alone may not provide the stability required to withstand spinal loads,”<sup>91</sup> and then states that “the spacers of this invention stimulate bone ingrowth like a bone graft and provide sufficient strength to support the vertebral column but avoid the disadvantages of both bone graft

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<sup>88</sup> Id.

<sup>89</sup> MPEP §2143.02.

<sup>90</sup> Exhibit 30, at p. 5, Evidence Appendix.

<sup>91</sup> Exhibit 33, at Col. 3, lns 18-19, Evidence Appendix.

and metal implants....”<sup>92</sup> Similarly, the Siebels reference describes that the fiber reinforced plastic implants disclosed therein “are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.”<sup>93</sup> Thus, while the Coates and Siebels references each describe that their own implants provide the necessary strength, neither one provides a basis from which it could be concluded that cortical bone pieces connected by cortical bone pins would successfully provide this property.

Because the combination of references in the pending obviousness rejection is not based upon any reasonable expectation of success, obviousness has not been established and the rejection should be withdrawn.

**D. The Combination of Siebels and Coates Does Not Teach All Of The Elements of Claims 26-30**

Claims 26-30 each recite pins “comprising cortical bone”<sup>94</sup> The pending obviousness rejection of pending claims 26-30 is improper because Coates and Siebels do not teach pins having the elements recited in any of these claims. “When evaluating claims for obviousness under 35 U.S.C. 103, all the limitations of the claims must be considered and given weight.”<sup>95</sup>

The Office Action has asserted that “it would have been obvious to make the disks and pins of the Siebels implant out of the cortical bone for the same reason Coates teaches doing the same.”<sup>96</sup>

As an initial matter, the only materials described in the Siebels reference from which the disks and/or anchoring pins described therein can be made are “fiber reinforced plastic”<sup>97</sup> and

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<sup>92</sup> Exhibit 33, at Col. 5, lns 21-24, Evidence Appendix. (Emphasis added).

<sup>93</sup> Exhibit 32, English translation at p. 3, Evidence Appendix. (Emphasis added.)

<sup>94</sup> Claims 26-30, Claims Appendix.

<sup>95</sup> MPEP §2143.03.

<sup>96</sup> Exhibit 30, at p. 3, Evidence Appendix.

<sup>97</sup> Exhibit 32, at p. 3, Evidence Appendix.

“carbon-fiber reinforced plastic.”<sup>98</sup> For example, on page 6, the Siebels reference states that “the disks are made of a carbon-fiber reinforced plastic (CFRP) whereby the anchoring means – according to the design of the implant – can consist of the same, or another material.”<sup>99</sup> The Siebels reference, however, does not describe any other suitable materials from which the anchoring pins of Siebels can be made. Nor is there any discussion of the parameters or factors that should be considered when choosing the material from which to make the anchoring pins. There is thus no teaching within the Siebels reference to guide one of ordinary skill in the art in choosing any material for the anchoring pins other than carbon-fiber reinforced plastic.

Additionally, the teachings of the Coates reference, either alone or in combination with the teachings of Siebels, would not render pins of cortical bone obvious. Coates fails to teach an implant having more than one portion capable of being connected by a pin.<sup>100</sup> Instead, Coates teaches an implant made from a single piece of cortical bone.<sup>101</sup> The Coates reference thus does not provide any basis for utilizing pins, much less pins of cortical bone.

Furthermore, the Coates reference also discusses many disadvantages with respect to the use of bone, including expressing concerns regarding the compressive strength and stability of bone implants, and states that developing a suitable implant “has been extremely difficult or impossible.”<sup>102</sup> In view of these teachings, the Coates reference does not provide any basis for utilizing pins of cortical bone such as those recited in pending claims 26-30.

## CONCLUSION

In view of the arguments and evidence provided herein by the Appellants, all bases for the rejection of claims 26-30 under 35 U.S.C. § 103(a) with respect to Siebels in view of Coates

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<sup>98</sup> Exhibit 32, at p. 6, Evidence Appendix.

<sup>99</sup> Exhibit 32, at pp. 3 and 6, Evidence Appendix.

<sup>100</sup> Exhibit 33, Evidence Appendix.

<sup>101</sup> See, e.g., Exhibit 33, at Col. 11, lns 41-61, Evidence Appendix.

<sup>102</sup> See, e.g., Exhibit 33, at Col. 2, ln 66 to Col. 3, ln 39, Evidence Appendix.

have been rebutted. Thus, the Appellants respectfully request the withdrawal of all bases for rejection and the allowance of pending claims 26-30.

Appellants believe that a fee of \$500.00 is currently due under 37 C.F.R. §41.20(b)(2) in conjunction with the filing of this brief. The Commissioner is authorized to charge the amount of \$500.00, and any additional fees that may be due, or to credit any overpayment, to account number 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Dated: September 30, 2008

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By: /Sarah A. Kofflin/  
Sarah A. Kofflin  
Registration No. 60,218  
Attorney for Appellants  
500 West Madison Street  
34th Floor  
Chicago, Illinois 60661  
(312) 775-8000

## CLAIMS APPENDIX

## CLAIMS APPENDIX

A complete listing of the text of the appealed claims is provided as follows:

26. An assembled bone graft, said assembled bone graft assembled outside the body and suitable for implantation into a human patient, said assembled bone graft comprising: a plurality of machined allograft bone portions layered to form a graft unit, and pins comprising cortical bone traversing said graft unit for holding said graft unit together as an assembled bone graft, wherein said assembled bone graft does not include an adhesive.

27. An assembled bone graft suitable for implantation in a human patient comprising:

two distinct bone portions of cortical bone, and pins comprising cortical bone, wherein said two distinct bone portions are machined allograft bone portions processed to be suitable for implantation in a human patient, said pins are of appropriate diameter and press fitted into machined holes in said two bone portions to hold together said two bone portions to form an assembled bone graft suitable for implantation in humans.

28. An assembled bone graft suitable for implantation in a human patient comprising two or more distinct bone portions of machined allograft bone and pins comprising cortical bone, said two or more distinct bone portions having holes therein for receiving said pins, said pins keeping said two or more distinct bone portions aligned and connected to form said assembled bone graft free of an adhesive and suitable for implantation in a human.

29. The assembled bone graft of claim 28 where there are two distinct bone portions of machined allograft bone.

30. The assembled bone graft of claim 28, wherein said two or more distinct bone portions are selected from the group consisting of: cortical bone and cancellous bone.

## EVIDENCE APPENDIX

**EVIDENCE APPENDIX**  
**Statement Regarding Evidence Entered**

The Evidence Appendix contains Exhibits 1-33, each of which is part of the prosecution history in this matter and has been entered into the record. The Exhibits are individually listed below, along with a notation regarding the date that each Exhibit was made of record. The dates listed as the Record Date below include the mailing date for Office Actions and other documents from the Patent Office, the filing date for Responses and other documents filed by Applicants, and the date on which references were first relied upon in forming a rejection.

<b>Exhibit ID</b>	<b>Exhibit Content</b>	<b>Record Date</b>
Exhibit 1	Application as Filed	February 12, 2001
Exhibit 2	Notice to File Missing Parts of Nonprovisional Application	March 19, 2001
Exhibit 3	Response to Notice to File Missing Parts of Application	May 21, 2001
Exhibit 4	Submission of New Formal Drawings	July 23, 2001
Exhibit 5	Preliminary Amendment	July 25, 2001
Exhibit 6	Office Action (Election/Restriction)	July 31, 2003
Exhibit 7	Response to Restriction Under 35 U.S.C. §121	August 22, 2003
Exhibit 8	Office Action	November 4, 2003
Exhibit 9	Amendment and Response Under 37 C.F.R. §1.111	May 4, 2004
Exhibit 10	Office Action	July 23, 2004
Exhibit 11	Amendment and Response Under 37 C.F.R. §1.116	November 19, 2004
Exhibit 12	Advisory Action	December 8, 2004
Exhibit 13	Transmittal of Substitute Drawings Requested by The Examiner	December 9, 2004
Exhibit 14	Advisory Action	January 4, 2005
Exhibit 15	Request for Continued Examination Under 37 C.F.R. § 1.114	January 20, 2005
Exhibit 16	Office Action	March 24, 2005
Exhibit 17	Amendment and Response Under 37 C.F.R. §1.111	July 15, 2005
Exhibit 18	Office Action	September 27, 2005
Exhibit 19	Request for Continued Examination Under 37 C.F.R. § 1.114	November 21, 2005

Exhibit 20	Office Action	February 27, 2006
Exhibit 21	Amendment and Response Under 37 C.F.R. §1.111	August 25, 2006
Exhibit 22	Office Action	October 25, 2006
Exhibit 23	Amendment and Response Under 37 C.F.R. §1.111	February 26, 2007
Exhibit 24	Office Action	May 3, 2007
Exhibit 25	Amendment and Request for Consideration	November 5, 2007
Exhibit 26	Office Action (Notice of Non-Compliant Response)	January 15, 2008
Exhibit 27	Office Action (Notice of Non-Compliant Response)	March 3, 2008
Exhibit 28	Response to Notice of Non-Compliant Amendment	January 25, 2008
Exhibit 29	Response to Notice of Non-Compliant Amendment	March 24, 2008
Exhibit 30	Office Action	April 4, 2008
Exhibit 31	Notice of Appeal	July 1, 2008
Exhibit 32	Translation of European Patent Application NO. 0517030	February 27, 2006
Exhibit 33	U.S. Pat. No. 5,989,289	February 27, 2006

## **EXHIBIT 1**

Please type a plus sign (+) inside this box →



PTO/SB/05 (4/96)

Approved for use through 09/30/2000. OMB 0651-0032  
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**UTILITY  
PATENT APPLICATION  
TRANSMITTAL**

(Only for new nonprovisional applications under 37 C.F.R. § 1.33(a))

Attorney Docket No. RTI-112R

First Inventor or Application Identifier Bianchi

Title ASSEMBLED IMPLANT

Express Mail Label No. EF205915955US

**APPLICATION ELEMENTS**

See MPEP chapter 600 concerning utility patent application contents.

1. ☒ \* Fee Transmittal Form (e.g., PTO/SB/17)  
(Submit an original and a duplicate for fee processing)
2. ☒ Specification (preferred amendment set forth below) [Total Pages 26]
- Descriptive title of the invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the invention
- Brief Summary of the invention
- Brief Description of the Drawings (if filed)
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 14]

4. Oath or Declaration [Total Sheets 3]

- a. ☐ Newly executed (original or copy)
- b. ☐ Copy from a prior application (37 C.F.R. § 1.63 (d))  
(for continuation/divisional with Box 16 completed)
- i. ☐ DELETION OF INVENTOR(S)  
Signed statement attached denoting  
inventor(s) named in the prior application,  
see 37 C.F.R. §§ 1.63 (d)(2) and 1.33 (b).

**NOTE FOR ITEMS 1 & 15:** IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY  
FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.70, 1.80(c)).  
IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28)

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:

Continuation ☐ Divisional ☒ Continuation-in-part (CIP) ☐ of prior application No. See Declaration

Prior application information. Examiner: \_\_\_\_\_ Group/Art Unit: \_\_\_\_\_

**For CONTINUATION or DIVISIONAL APPS only:** The entire disclosure of the prior application, from which as such or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

**17. CORRESPONDENCE ADDRESS**☐ Customer Number or Bar Code Label (Insert Customer No. or Attach bar code label here) or ☐ Correspondence address below

Name Gerard H. Bencen  
Address Bencen & Van Dyke, P.A., 1630 Hillcrest Street, Orlando, Florida 32803 USA  
Telephone 407-228-0328 Fax 407-228-0329

I hereby certify that this correspondence is being deposited with the US Post Office with sufficient postage in an Express Mail envelope, Express Mail No. EF205915955US, addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on 2/12/2001

Gerard H. Bencen, Reg. No. 35746

Name (Print/Type)	Gerard H. Bencen	Registration No. (Attorney/Agent)	35746
Signature	<i>Gerard H. Bencen</i>	Date	Feb 12, 2001

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# FEE TRANSMITTAL for FY 2000

Patent fees are subject to annual revision.  
 Small Entity payments must be supported by a small entity statement,  
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 See 37 C.F.R. §§ 1.27 AND 1.28

TOTAL AMOUNT OF PAYMENT (\$4256.00)

## Complete if Known

Application Number N/A  
 Filing Date 2/12/2001  
 First Named Inventor Bianchi et al.  
 Examiner Name Unknown  
 Group/Art Unit Unknown  
 Attorney Docket No. RTI-112R

## METHOD OF PAYMENT (check one)

1. The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

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Charge Any Addressed Fee Required Under 37 CFR §§ 1.16 and 1.17

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## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity Fee Code (S)	Small Entity Fee Code (S)	Fee Description	Fee Paid
101	690	251 345 Utility filing fee	710.00
106	310	206 155 Design filing fee	
107	480	207 240 Plant filing fee	
108	690	208 345 Provisional filing fee	
114	150	214 75 Provisional filing fee	

SUBTOTAL (1) (\$710.00)

### 2. EXTRA CLAIM FEES

Total Claims Independent Claims	Extra Claims Fee Code (S)	Fee Description	Fee Paid
61	20**	41 X	738.00
39	34**	36 X	2808.00

Multiple Dependent

\*\*or number previously paid, if greater; For Reissues, see below

Large Entity Fee Code (S)	Small Entity Fee Code (S)	Fee Description
103	18 203	9 Claims in excess of 20
103	78 302	39 Independent claims in excess of 3
104	260 204	130 Multiple dependent claim, if not paid
109	78 209	39 **Reissue independent claims over original patent
110	18 210	9 **Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$3546.00)

## FEE CALCULATION (continued)

Large Entity Fee Code (S)	Small Entity Fee Code (S)	Fee Description	Fee Paid
105	130 205	45 Surcharge - late filing fee or oath	
127	50 227	25 Surcharge - late provisional filing fee or cover sheet	
139	130 139	130 Non-English specification	
147	2,520 147	2,520 For filing a request for reexamination	
112	920*	112 920* Requesting publication of SIR prior to Examiner action	
113	1,840*	113 1,840* Requesting publication of SIR after Examiner action	
115	110 215	55 Extension for reply within first month	
116	380 216	190 Extension for reply within second month	
117	870 217	435 Extension for reply within third month	
118	1,360 218	680 Extension for reply within fourth month	
128	1,850 228	925 Extension for reply within fifth month	
119	300 219	150 Notice of Appeal	
120	300 220	150 Filing a brief in support of an appeal	
121	250 221	130 Request for oral hearing	
138	1,510 138	1,510 Petition to institute a public use proceeding	
140	110 240	55 Petition to revive - unavoidable	
141	1,210 241	605 Petition to revive - unintentional	
142	1,210 242	605 Utility issue fee (or reissue)	
143	430 243	215 Design issue fee	
144	580 244	290 Plant issue fee	
122	130 122	130 Petitions to the Commissioner	
123	50 123	50 Petitions related to provisional applications	
126	240 126	240 Submission of information Disclosure Sheet	
581	40 581	40 Recording each patent assignment per property (three number of properties)	
146	690 246	345 Filing a submission after final rejection (37 CFR § 1.125(a))	
149	690 249	345 For each additional invention to be examined (37 CFR § 1.129(b))	

Other fee (specify) \_\_\_\_\_

Other fee (specify) \_\_\_\_\_

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SUBTOTAL (3) (\$6.00)

## SUBMITTED BY

Name (Print/Type) Gerard H. Bencen Registration No. 35746 Telephone 407-228-0328  
 Signature  Date 7/2/01

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1  
TITLE OF THE INVENTION  
ASSEMBLED IMPLANT

CROSS REFERENCE TO RELATED APPLICATION

5 This application is a continuation-in-part of pending provisional application serial number 60/181,622, filed February 10, 2000, pending, and of application serial numbers 09/191,132, filed on November 13, 1998, pending; and of 09/378,527, filed on August 20, 1999, pending; and of 09/370,194, filed on September 7, 1999, pending; 29/123,227, 10 filed May 12, 2000, pending; the priority of all of which is claimed herein under 35 U.S.C. Section 120.

FIELD OF THE INVENTION

15 This invention relates to implants and methods for their preparation wherein components of the implant are assembled from constituent pieces to produce a complete implant.

BACKGROUND OF THE INVENTION

20 In the field of medicine, there has been an increasing need to develop implant materials for correction of biological defects. Particularly in the field of orthopedic medicine, there has been the need to replace or correct bone, ligament and tendon defects or injuries. As a result, there have emerged a number of synthetic implant materials, including but not limited to metallic implant materials and devices, devices composed in whole or in part 25 from polymeric substances, as well as allograft, autograft, and xenograft implants. It is generally recognized that for implant materials to be acceptable, they must be pathogen-free, and must be biologically acceptable. Generally, it is preferable if the implant materials may be remodeled over time such that autogenous bone replaces the implant materials. This goal is best achieved by utilizing autograft bone from a first site for 30 implantation into a second site. However, use of autograft materials is attended by the significant disadvantage that a second site of morbidity must be created to harvest

autograft for implantation into a first diseased or injured site. As a result, allograft and xenograft implants have been given increasing attention in recent years. However, use of such materials has the disadvantage that human allograft materials are frequently low in availability and are high in cost of recovery, treatment and preparation for implantation.

By contrast, while xenograft implant materials, such as bovine bone, may be of ready availability, immunological and disease transmission considerations imply significant constraints on the ready use of such materials.

In view of the foregoing considerations, it remains the case that there has been a long felt need for unlimited supplies of biologically acceptable implant materials for repair of bone and other defects or injuries. This invention provides a significant advance in the art, and largely meets this need, by providing materials and methods for production of essentially any form of implant from component parts to produce assembled implants.

In recent months, there have appeared several patents and patent publications which address similar or-identical considerations to those to which the present invention disclosure is directed. Specifically, reference is made to PCT publication WO00/40177, which published on 13 July 2000, the disclosure of which is hereby incorporated by reference as if fully set forth herein.

In addition, reference is made herein to US Patent 5,899,939 to Boyce, which issued on May 4, 1999, the disclosure of which is hereby incorporated by reference as if fully set forth herein.

Finally, reference is made herein to US Patent 6,025,538 to Yaccarino, which issued on February 15, 2000, the disclosure of which is hereby incorporated by reference as if fully set forth herein.

### SUMMARY OF THE INVENTION

This invention provides a method for manufacture of autograft, allograft and xenograft implants which comprises assembling such implants from smaller pieces of graft materials to form a larger graft implant product.

Accordingly, it is one object of this invention to provide a method for assembly of multiple bone implant shapes from smaller bone implant pieces.

Another object of this invention is to provide assembled bone implants.

Another object of this invention is to provide a method whereby otherwise wasted tissue may be used in the production of useful orthopedic implants.

Further objects and advantages of this invention will be appreciated from a review of the complete disclosure and the appended claims.

### BRIEF DESCRIPTION OF THE DRAWINGS

Attached to this invention disclosure are a large number of sketches which demonstrate a wide variety of assembled implants which may be prepared and used according to this invention.

Figure 1 is a flow chart showing the formation of various sub-component parts of an assembled implant according to this invention, from which assembled implants and a kit comprising these parts may be formed according to the disclosure of this invention.

Figure 2 provides a schematic of an assembled implant according to this invention.

Figure 3 provides a schematic of an assembled implant according to this invention.

Figures 4-7 provides a schematic of an assembled implant according to this invention.

Figures 8-9 provides a schematic of an assembled implant according to this invention.

Figures 10-14 provides a schematic of an assembled implant according to this invention.

Figures 15-18 provides a schematic of an assembled implant according to this invention.

Figure 19 provides a schematic of an assembled implant according to this invention.

Figure 20 provides a schematic of an assembled implant according to this invention.

Figure 21 provides a schematic of an assembled implant according to this invention.

5 Figure 22 provides a schematic of an assembled implant according to this invention.

Figure 23 shows the assembly of a dowel from component pieces.

Figure 24 shows the reinforcement of an implant using a cortical bone pin.

Figure 25 shows the reinforcement of an implant using a cortical bone pin and a cortical bone disk.

10 Figure 26 shows the reinforcement of cancellous bone implants using a plurality of cortical bone pins.

Figure 27 shows the formation of an assembled implant comprising soft and hard tissues.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

15 Currently, autograft, allograft and xenograft products are produced as solid, continuous materials. For example, bone dowels (see US Patent 5,814,084, hereby incorporated by reference), Smith-Robinson cervical spine implants, iliac crest grafts, and the like are harvested and machined from single, continuous pieces of bone. The present invention  
20 provides methods for manufacture of autograft, allograft and xenograft implants by assembling such implants from smaller pieces of graft materials to form a larger graft implant product. As a result, increased utilization of valuable implant materials is achieved, thereby more effectively meeting the ever-increasing demands for graft implant materials. In addition, greater flexibility is achieved in the types and shapes of implant  
25 materials is achieved. Essentially, any implant piece that may be required may be formed according to the present invention, and orthopedic surgeons may be provided with kits of assemblable parts which may be formed in the course of a surgical procedure to precisely meet the needs of a given patient or procedure. In yet another aspect of this invention, existing graft products may be strengthened or reinforced by assembly of different types  
30 of graft materials into an assembled product. One example of such a reinforced product is a cancellous wedge, block, dowel or the like into which is inserted reinforcing pins of

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cortical bone. As a result, those skilled in the art will understand from this disclosure that different sections of tissue may be assembled to make a complete graft implant.

Furthermore, this invention provides for the product of assembled implants comprising any one or combinations of allograft materials, autograft materials, xenograft materials, synthetic materials, metallic materials and the like. Furthermore, the assembled implants or the component pieces which are combined to form the assembled implant may be pre-treated or treated after assembly to incorporate any desired biologically active or inert materials. Thus, for example, in an assembled bone dowel implant according to this invention, the assembled bone dowel comprises segments of cortical bone pinned to each other by means of cortical bone pins. Prior to assembly or after assembly, the graft materials are soaked, infused, impregnated, coated or otherwise treated with bone morphogenetic proteins (BMP's), antibiotics, growth factors, nucleic acids, peptides, and the like.

It will be appreciated that variously shaped wafers, blocks, rings, washer-shaped bone pieces and the like may be affixed to each other in any secure and biologically acceptable manner. Preferably, the assembled pieces of bone are affixed to each other by means of pins, screws, rods, interference fit, threaded fits, key-way fit, and the like made from cortical bone. These fixation pieces are machined in a CNC lathe or the like to appropriate dimensions and are then threaded into mating holes tapped in the pieces to be assembled, or are pressed into drilled holes through adjacent pieces to be assembled by a pneumatic press or the like. In this fashion, very strong and tightly fitted pieces of implant materials may be joined and implanted. The assembled pieces may first be machined to desired dimensions and shapes, prior to assembly, the assembled implant may be machined, or both.

As noted above, the implant according to this invention may comprise an assembled cancellous block, dowel or the like, harvested from the iliac crest or another suitable site. As is known in the art, due to the wafer-like structure of cancellous bone, such grafts have low load-bearing characteristics. There exist reports in the literature of instances of extrusion, expulsion or collapse of iliac crest wedges, Cloward Dowels, and the like when

utilized, for example, in spinal fusions. Nonetheless, use of cancellous bone is preferable over use of cortical bone implants, since cancellous bone is more osteoconductive than cortical bone. According to this invention, a Cloward Dowel, iliac crest wedge, or cancellous bone block, dowel or the like is reinforced by insertion therein of cortical bone pins. According to the method of this invention, cortical implants may also be reinforced by insertion therein of cortical bone pins, including when an assembled implant is prepared comprising different segments of cortical bone, cancellous bone or both. Insertion of the reinforcing pins provides an implant with multiple load-bearing pillars. The pins may be made to protrude from the surface of the implant to engage with inferior, superior or both surfaces of bone between which the implant is inserted. Thus, in a spinal implant, pin protrusions may be employed to create contact between the implant and the vertebral bodies, thus preventing extrusion and reinforcing a secure fit of the implant between adjacent vertebrae. We have, surprisingly, found that cortical pins of about 4.5 mm in diameter may each support a load of up to about 2700 newtons (160 Mpa). Thus, according to the method of this invention, multiple pins may be inserted into an implant to produce a load-bearing capacity of known proportions (e.g. 10,000 newtons by insertion of five pins).

A further advantage of this invention is that it permits use of tissues that are not currently amenable to standard autograft, allograft or xenograft harvesting and processing procedures, such as ribs, metatarsal bone and the like. In addition, useful implant materials may be harvested and produced from otherwise un-useable donor tissues. In addition, due to the different nature of various segments of bone that are incorporated into the assembled, reinforced implants of this invention, various shaping methods aside from CNC lathe or other known procedures may be applied to different segments of the implant. Thus, a cancellous portion of bone implant may be compression molded, and then affixed to other portions of cortical or cancellous bone machined according to different or similar principles. In addition, due to the ability provided by this invention to assemble implant pieces, implants of unusual sizes and dimensions may be prepared and machined. Thus, implants of 100 mm in size could be machined, for example, for

corpectomies, when otherwise bone stock for manufacture of such implant dimensions would not be available.

In view of the present disclosure, it will be appreciated that this invention provides a wide  
5 variety of assembled implants and implant parts: dowel shaped implants comprising  
assembled dowel segments, between about two to about ten segments, pinned together by  
one or more cortical bone pins. The assembled segments may closely abut each other or  
may be spread apart from each other. Such implants may be prepared by harvesting disks  
of cortical bone, drilling and optionally tapping holes therein, and inserting shafts of  
10 cortical pins therethrough, or therein, optionally by threading portions thereof for  
torquing into optionally tapped holes. The thus produced dowels may be tapered or have  
parallel sides. In addition, dowels which are harvested as a cross-section across the  
intramedullary canal of a long bone, as in US Patent 5, 814,084, which might otherwise  
not pass production specifications, due to penetration of one outside wall into the  
15 intramedullary canal, may be completed by insertion therein of a cortical pin. Likewise,  
where a sidewall is otherwise considered to be too narrow, a "doughnut" of bone may be  
affixed to the sidewall by means of a cortical pin. A longer dowel may be prepared by  
affixing two dowels to each other. A posterior longitudinal interbody fusion implant  
(PLIF) may be machined from a single piece of cortical bone, or be assembled from two  
20 pieces of bone which are affixed to each other by means of a cortical pin. A bone screw  
may also be prepared according to the method of this invention by affixing multiple  
pieces of cortical bone to each other with a cortical bone pin, and then machining a thread  
on the exterior of the assembled bone pieces. It will further be appreciated from this  
disclosure that different portions of the assembled implant may be demineralized, to  
25 achieve a level of elasticity or compressibility not otherwise present in cortical or  
cancellous bone. Different portions of bone may also be retained on a shaft by means of  
a cotter-pin type device.

In addition to assembled implants, instruments may be conveniently prepared according  
30 to the methods of this invention which may be utilized for insertion of other implants. In  
one embodiment of this invention, therefore, an implant driver is produced wherein the

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Referring now to figure 1, there is shown a flow-chart representing various elements that may be processed and assembled according to this invention. Cortical bone pins 100 are used to assemble a series of bone disks 101 into a pre-part 102 which is then machined into a series of final products: Threaded dowels, 103; small blocks 104; unique shapes, 105 such as a "wedding-cake" like shape wherein disks bearing threads are spaced apart from each other leaving voids 105\* into which additional materials may be inserted, with the disks retained in fixed relation to each other by means of the through pins 100; tapered dowels 106; screws 107; smooth cylinders 108; or large blocks 109. From this figure, it will be appreciated that a central concept relevant to the present invention is the ability to machine smaller parts of tissue, specifically bone tissue, such as cortical bone, cancellous bone, cortical-cancellous bone, portions of which may be demineralized (see, for example, US Patent 6,090,998, hereby incorporated herein by reference for this purpose), and assemble these portions of tissue using, preferably, cortical bone pins. The assembled tissue pieces may be machined prior to assembly, and then, upon assembly, a complete implant is ready for implantation. Alternatively, the tissue pieces may first be assembled, and the assembled pieces may then be machined into any desired final form. The order of assembly and machining will be determined by the specific forms of implant required for a particular application. In figure 1, a series of pre-machined tissue forms are disclosed, which may conveniently be included in a kit for use as needed by an orthopedic surgeon. Thus, for example, where a particular implant of specific dimensions is required, the surgeon is able to select pre-shaped implant segments to fill a particular geometric space and shape in the spine of an implant recipient. Numerous permutations and combinations of implant pieces for assembly are possible, based on the pre-machined assemblable implant pieces included in such a kit, and those skilled in the art will appreciate that the skilled orthopedic surgeon will be able to create implants as needed when supplied with such a kit. Thus, a preferred kit includes disks of bone, cortical bone, cancellous bone, allograft or xenograft, also referred to herein as "washers" or "doughnuts" such that a center hole is provided for press-fitting or screwing on of the disks to a cortical bone or synthetic or metallic shaft or pin. The disks may be demineralized, mineralized, or partially demineralized. Also desirable in such a kit are plugs of cortical bone, cancellous bone, or cortical-cancellous bone, including at least one

through hole, and optionally more than one such through-hole, for insertion of pins therethrough. Ovals, squares, rectangles and irregular shapes may also be provided in certain kits for specific applications. It will further be appreciated, based on the present disclosure, that inclusion of a bone paste, such as that disclosed in WO99/38543, hereby  
5 incorporated by reference, may be beneficial for filling any voids that remain, and to implant with the assembled implant, osteogenic material, (i.e. osteoconductive material, Osteoinductive material, or both, as well as material that assists in adhering the implant to the site of implantation). Further, a molded implant may be combined with the assembled implant of this invention. A preferred molded implant for orthopedic  
10 applications is disclosed in PCT publication WO 00/54821, the disclosure of which is hereby incorporated by reference.

With reference to figure 2, there is shown two machined-bone pieces, T and Z each of which bear external threading X and holes Y into which pins A are inserted to form the assembled graft 200. As can be seen, the assembled graft 200 comprises a void, 201 into  
15 which osteogenic material may be inserted prior to or after implantation. The pins Y may be metal pins, but preferably are pins machined from cortical bone. This enables the entire implant to remodel into autogenous tissue over time, such as vertebral bone, when the implant 200 is inserted into the intervertebral space. The graft 201 is also shown with a groove, 202 in which a driver may be inserted to provide rotational torque for insertion of the implant. An instrument attachment hole, 203, is also provided, to ensure that the implant remains securely on the head of the driver means in the process of surgical  
20 implantation. Naturally, those skilled in the art will appreciate that the segments Z and T may be brought into close abutment with each other, thereby eliminating the space 201.

25 In that event, the length of the pins A would be modified to prevent unnecessary protrusion, although in some applications, protrusion may be useful when driving the implant 200 into place. It will also be appreciated that the number of pins used, while represented as two in this figure, may be fewer or more in number, depending on the particular application, the extent of torsional or compressive loads, and the like  
30 anticipated to be experienced by the implant once *in situ*.

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Figure 3 shows an implant assembled from three principal segments **F**, **D**, and **E**, which are held together by pins **300**. In this implant, the waffle-shaped structure of implant segment **D** is intended to represent the use of cancellous bone, which is abutted on either side by cortical bone, which forms segments **F** and **E**. The fully assembled implant is shown in figure 4, while figures 5, 6 and 7 show end-on views, and cross sectional views A-A and B-B, respectively. Those skilled in the art will appreciate from this disclosure that segment **F**, segment **D**, or segment **E** may be demineralized according to methods known in the art. Likewise, all of these segments may be demineralized. Where a flexible implant is required, the implant may be assembled, and the entire implant may be demineralized.

Figure 8 shows an embodiment of this invention wherein rectangular bone segments **N** and **G** are assembled into implant **900**, shown in figure 9. Features **901** and **902** which comprises ridges, teeth, or other external features are machined into the superior and inferior faces of the implants in order to assist in retention of the implants once placed *in situ*.

Figures 10-14 show the assembly of elements **J**, **H**, and **I** into implant **1100**, shown end-on, in cross-section A-A and B-B, in figures 12-14, respectively. As can be seen, bone element **H** is shown with a waffle-like-structure, to represent that this element may be cancellous bone, demineralized bone, a polymer composite, such as poly-L-Lactic acid, polyglycolic acid, or the like. Features **1101** and **1102** represent external grooves or teeth machined into the superior and inferior surfaces of the implant to assist in retention of the implant once placed *in situ*.

Figures 15-18 show the assembly of elements **M**, **K**, and **L**, each of which is a substantially cubic bone element, using pins **1500**. Figure 17 is a top view, showing cross section A-A, represented in figure 18, with the final assembled implant **1600** shown in figure 16.

Figure 19 shows a "Wedding-Cake" design of an implant 1900 assembled from units A-C, pinned together by pins a-c. Void area 1901 is available for filling with osteogenic materials.

Figure 20 shows implant 2000 which is an assembled Cervical Smith Robinson implant similar to that shown in PCT publication WO99/09914, hereby incorporated by reference, except that this implant is fashioned from a series of assembled bone pieces 2001 and machined into the desired final shape.

Figure 21 shows implant 2100 assembled from two cortical bone pieces and one cancellous bone piece, and pinned together. The implant has an anterior height H1 which is smaller than posterior height H2, which permits retention of correct spinal lordosis upon implantation, for example, in a posterior lumbar intervertebral implant fixation procedure. Superior and inferior features 2101, 2102 prevent expulsion of the implant once place *in situ*.

Figure 22 shows an implant 2200 assembled from a series of sub-implant pieces 2201. The implant may contain cancellous bone 2202 segments; as well as cortical bone 2203 segments and cortical bone pins 2204.

Figure 23 shows the formation of a tapered dowel 2300 by assembling "doughnut" or "disk" or "washer" shaped bone pieces 2301 on a cortical bone shaft 2302 by using washer pieces of differing diameter. This figure only shows two disks, but a continuous dowel is formed by using disks of a graded diameter between each end of the cortical bone shaft 2302. In figure 24, figure 24A shows a bone dowel in which one sidewall of a bone dowel 2400 such as that disclosed and claimed in US Patent 5,814,084, hereby incorporated by reference, is "out of specifications" due to being too narrow or absent. This is repaired in figure 24B according to this embodiment of the invention by incorporation of an allograft or xenograft cortical bone pin 2401, to form a complete bone dowel. In this manner, valuable biological material which might otherwise be unusable

for a particular application may be salvaged for use by employing the methodology of this invention.

In figure 25, a similar procedure for salvaging a dowel 2500 is shown whereby a pin 2501 is driven through the center of the dowel 2500 to reinforce the dowel longitudinally. Furthermore, where an endcap 2503 of the dowel is "out of spec" for being too narrow, the endcap is reinforced by press-fitting a cortical bone disk 2502 onto the end of the pin 2501.

In figure 26, a series of cancellous bone implants 2600 are reinforced by inclusion therein of a series of cortical pins 100. Each cortical pin of a 2 mm diameter has been found to support approximately 2000 newtons of axial compressive load. Accordingly, cancellous bone implants of essentially any desired height and compressive strength may be assembled in this manner by affixing several layers of cancellous bone with cortical bone pins. Naturally, based on this disclosure, those skilled in the art will appreciate that other materials may be included in such a "sandwich" of bone materials. The cancellous bone may be soaked in a solution containing growth factors, such as, but not limited to, bone morphogenetic proteins, fibroblast growth factors, platelet derived growth factor, cartilage derived morphogenetic proteins, stem cells, such as mesenchymal stem cells, osteoprogenitor cells, antibiotics, antiinflammatory compounds, anti-neoplastic compounds, nucleic acids, peptides, and the like. Those skilled in the art will also appreciate that layers of cortical bone may be included, layers of biocompatible synthetic polymers and the like may also be included in the stacked bone implant. Various shapes may also be built upon, using for example, circles, ellipses, squares, and the like, as necessary for a given application.

In a further aspect of the present invention, the assembled implant is driven by cortical pins to seat in an implant site, using a driver that engages cortical bone pins with purchase sites on the implant. Thus, for example, not meant to be limiting, the driver may comprise a handle with projecting cortical pins which engage with holes in the assembled allograft, thereby providing a site for torquing the implant into position.

In a further embodiment according to this invention, assembled cortical bone blocks, or cortical cancellous bone blocks are assembled in combination with wedged or pinned soft tissue, such as tendon, ligament, skin, collagen sheets, or the like, to create grafts similar

to naturally occurring tissue sites, such as the bone-tendon interface found at the patella. Such combination implants permit reconstruction of sites such as the Anterior Cruciate Ligament (ACL) or Posterior Cruciate Ligament (PCL). According to this embodiment of the invention, a ligament or tendon or skin or collagen sheet membrane is pinned between adjacent blocks of cortical bone. Accordingly, various implants, such as known bone-tendon-bone implants which are in short supply may be supplanted by assemblage of an implant comprising assembled bone blocks, between which is fixed a ligamentous tissue, including but not limited to ligament, tendon, demineralized bone, and the like.

Referring to figure 27, there is shown one example of this embodiment of the present invention in which an implant 2700 is assembled from a superior bone block 2701, an inferior bone block 2702 and a wedged flexible tissue, such as a ligament or tendon or portion of demineralized bone, 2704, all of which are pinned together with cortical bone pins 2703 or other fixation means. Naturally, those skilled in the art will appreciate, based on this disclosure, that other shapes of bone blocks, such as rounded bone blocks, and other types of combinations of soft and hard tissues may be assembled according to this disclosure. However, the example of such an implant 2700 may be used instead of having to harvest a bone-tendon-bone implant from cadaveric knees, which tissue is in short supply.

Based on the present disclosure, those skilled in the art will further appreciate that the cortical bone pins disclosed herein may have features defined thereon for various applications. For example, not meant to be limiting, the shafts may contain stops, such that other pieces of bone inserted thereon can only travel a certain distance down the shaft before encountering the stop. The shaft may also contain through holes, to permit insertion of cotter pins or the like. Furthermore, the cortical bone shaft may be demineralized, mineralized, or partially demineralized. In one specific embodiment, the end of the cortical shaft contains a tapped cannulation a short distance into the

longitudinal end of the shaft. In this way, a screw may be driven into the cannulation to retain elements inserted over the shaft in association with the shaft. To accommodate the screw, the screw end bearing the cannulation may be partially demineralized, such that upon insertion of the retention screw, the shaft end does not shatter, but expands to accommodate the increasing diameter of the screw as it is driven into the shaft.

Naturally, in certain applications, it may be desirable for the cortical pins to be cannulated throughout the longitudinal length thereof. However, care should be taken that this does not unduly weaken the overall compressive or torsional strength of the assembled implant. This may be addressed by including pins that are not cannulated, along with pins that are cannulated. The cannulated pins may be used in combination with sutures or the like, in order to hold an implant in a specific orientation, until fusion with adjacent bone has proceeded to a sufficient extent for the implant to become stable without the sutures.

It will be appreciated from the present disclosure that implants that have classically been fabricated from metals may be fabricated by assembling bone pieces. In addition, a benefit of the assembled graft according to this invention is that the components of the assembled graft can be derived from various anatomical structures, thus circumventing limitations normally resulting from having to obtain a graft from a particular anatomical source of a particular donor. Not only can the components be sourced from different anatomies, but also different donors may yield various components for assembly into a unitary implant. The end result is maximization of the gift of donation and the preservation of precious tissue resources. As noted above, being able to pool tissues from different sources depends, to some significant extent, on the ability to treat portions of tissue harvested from different anatomies or donors so as to prevent any contamination of a recipient with pathological or antigenic agents. A further benefit of the present invention is that different implants with height or width limitations due to the anatomical structures from which the implant has been derived may be pinned together to form implants of essentially any desired dimensions. In this fashion, an inventory of building blocks in combination with the appropriate assembly pins, threaded or unthreaded, is useful to provide implants of essentially any dimensions in the course of given surgical

procedure. According to this embodiment of the invention, for example, a cervical Smith-Robinson (CSR) of any desired height may be produced by attaching two or more existing CSR implants together with cortical bone pins. This is accomplished preferably using two machined CSR's of known height such that when added together, the desired overall height is achieved. The two CSR's are stacked and drill holes are machined through the CSR bodies, following which the cortical bone pins are press-fit through the thus machined holes. Preferably, the diameter of the pins is slightly greater than the diameter of the drilled holes, such that a tight press-fit is achieved.

From the present disclosure, it will further be appreciated that implants according to this invention may be assembled in the operating room by a surgeon, using pre-formed implant pieces, from a kit. It will further be appreciated that the assembled implant pieces may be adhered to each other using any of a number of biologically acceptable glues, pastes and the like. In one such embodiment, the assembled implant pieces are assembled using a polymethyl-methacrylate glue, a cyanoacrylate glue, or any other adhesive known in the art, so long as the use of such an adhesive is confirmed to be non-toxic. It will further be appreciated that in forming the assembled grafts according to the present invention, it is acceptable, although not required, for interlocking features to be included on abutting faces of implant segments to be assembled together. Where such features are included, it is preferred for the adjacent features to be complementary, such that a protrusion on a first surface is met by a compatible indentation in the abutting surface. Such abutting features assist to provide torsional and structural strength to the assembled implant, and to relieve a measure of stress on the cortical bone pins used to assemble the implant.

According to US patent 6,025,538, an elaborate system is disclosed for ensuring that a bore is provided in mating surfaces of a composite implant such that the bore is angularly aligned with respect to mating surfaces so as to be oblique to the plane of each mating surface. This is not required according to the present invention.

According to US patent 5,899,939, layers of bone are juxtaposed, but no mechanical fixation of the various layers to each other is provided for, such as the cortical bone pins disclosed herein.

5 With respect to PCT Publication WO 00/40177 and the priority US Patent filings, serial nos. 09/225,299, filed 5 January 1999, 09/286,975, filed 6 April, 1999, and 09/368,263, filed 3 August 1999, it is believed that there exists interfering subject matter claimed in the present and in those applications. As to the interfering subject matter, claims are presented herein which are believed to constitute the basis for initiation of an interference proceeding in the United States, and initiation of such a proceeding is hereby specifically  
10 elicited, in which it is believed that the present applicants are entitled to priority. As to the non-interfering subject matter disclosed and claimed herein, the right to file one or more continuation or divisional applications free of interfering subject matter is reserved.

15 Having generally described this invention, including the methods of manufacture and use thereof, including the best mode thereof, those skilled in the art will appreciate that a large number of variations on the principles described herein may be accomplished. Thus, the specifics of this description and the attached drawings should not be interpreted to limit the scope of this invention to the specifics thereof. Rather, the scope of this  
20 invention should be evaluated with reference to the claims appended hereto.

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WHAT IS CLAIMED IS:

1. A method for manufacture of autograft, allograft and xenograft implants which comprises assembling such implants from smaller pieces of graft materials to form a larger graft implant product.
2. A kit comprising assemblable parts of autograft, allograft and xenograft implants for assembling such implants from smaller pieces of graft materials to form a larger graft implant product which may be formed in the course of a surgical procedure to precisely meet the needs of a given patient or procedure.
3. A method of strengthening or reinforcing autograft, allograft and xenograft implants which comprises assembling such implants from smaller pieces of graft materials to form a larger graft implant product.
4. The method of claim 3 wherein the reinforced product is cancellous bone into which is inserted reinforcing material.
5. The method according to claim 4 wherein said reinforcing material comprises cortical bone.
6. A graft implant comprising any one or combinations of allograft materials, autograft materials, xenograft materials, synthetic materials, metallic materials assembled into an assembled implant which is assembled into a single graft by use of reinforcing material to hold the constituent pieces of graft materials together.
7. The graft implant according to claim 6 wherein said reinforcing material comprises cortical bone.

- 1 8. The graft implant according to claim 6 wherein the assembled implant is pre-  
2 treated or treated after assembly to incorporate biologically active or inert  
3 materials.
- 1 9. An implant comprising segments of cortical bone, cancellous bone, cortical-  
2 cancellous bone, or combinations thereof pinned to each other by means of  
3 cortical bone pins, wherein, prior to assembly or after assembly, the graft  
4 materials are soaked, infused, impregnated, coated or otherwise treated with bone  
5 morphogenetic proteins (BMP's), antibiotics, growth factors, nucleic acids,  
6 peptides, or combinations thereof.
- 1 10. The implant according to claim 6 comprising an assembled cancellous block, or  
2 dowel, harvested from the iliac crest or another suitable site to form a Cloward  
3 Dowel, iliac crest wedge, or cancellous bone block, dowel, reinforced by insertion  
4 therein of cortical bone pins.
- 1 11. The implant according to claim 6 comprising a cortical bone implant reinforced  
2 by insertion therein of at least one cortical bone pin.
- 1 12. The implant according to claim 6 comprising an assembled implant comprising  
2 different segments of cortical bone, cancellous bone or both.
- 1 13. The implant according to claim 6 comprising an assembled implant comprising  
2 different segments of cortical bone, cancellous bone, demineralized cortical or  
3 cancellous bone, synthetic material, and combinations thereof.
- 1 14. The implant according to claim 13 wherein insertion of reinforcing pins provides  
2 an implant with multiple load-bearing pillars.
- 1

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15. The implant according to claim 14 wherein said pins protrude from the surface of the implant to engage with inferior, superior or both surfaces of bone between which the implant is inserted.
16. The implant according to claim 15 which is a spinal implant.
17. The implant according to claim 15 comprising a cancellous portion of bone implant that has been compression molded, and then affixed to other portions of cortical or cancellous bone machined according to different or similar principles.
18. The implant according to claim 6 in the form of a tapered dowel
19. A method of repairing a bone implant which comprises insertion therein of at least one cortical bone pin.
20. The method according to claim 19 which further comprises affixing a piece of bone to an existing bone implant by affixing said piece of bone to said cortical bone pin.
21. The method according to claim 1 for making an instrument for insertion of other implants.
22. The method according to claim 21 which is an implant driver.
23. A method for salvaging an implant that does not manufacturing specifications which comprises insertion of at least one cortical bone pin at a site to reinforce said site such that in combination with said at least one cortical bone pin, said implant meets manufacturing specifications.

- 1 24. An assembled implant comprising a first bone segment pinned to a second bone  
2 segment with a flexible tissue affixed between said first bone segment and said  
3 second bone segment.
- 1
- 1 25. The assembled implant according to claim 24 wherein said first and second bone  
2 segments are affixed to each other by means of at least one cortical bone pin.
- 1
- 1 26. A composite bone graft, comprising: a plurality of bone portions layered to form a  
2 graft unit, and one or more biocompatible connectors for holding together said  
3 graft unit, said biocompatible connectors do not comprise an adhesive.
- 1
- 1 27. A composite bone graft comprising:  
2 two or more distinct bone portions, and one or more biocompatible connectors,  
3 wherein said biocompatible connectors hold together said two or more bone  
4 portions to form said composite bone graft, said biocompatible connectors do not  
5 comprise an adhesive.
- 1
- 1 28. A composite bone graft comprising two or more connected, distinct, bone  
2 portions, said connected, distinct, bone portions do not comprise an adhesive.
- 1
- 1 29. A composite bone graft comprising three or more connected, distinct, bone  
2 portions, said connected, distinct, bone portions are not connected with an  
3 adhesive.
- 1
- 1 30. The composite bone graft of any one of claim 26, wherein said bone portions are  
2 selected from the group consisting of: cortical bone and cancellous bone.
- 1
- 1 31. A composite bone graft, comprising:  
2 a first bone portion;  
3 a second bone portion;  
4 a third bone portion, said first, second and third bone portions are layered to form  
5 a graft unit; and  
6 one or more biocompatible connectors for holding together said graft unit, said  
7 biocompatible connectors do not comprise an adhesive.
- 1
- 1 32. A composite bone graft, comprising:  
2 a first cortical bone portion;  
3 a second cortical bone portion;

a cancellous bone portion disposed between said first cortical bone portion and said second cortical bone portion to form a graft unit; and one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

33. A composite bone graft, comprising:

a first cortical bone portion;  
a second cortical bone portion provided on said first cortical bone to form a graft unit; and one or more biocompatible connectors, connecting said graft unit, said biocompatible connectors do not comprise an adhesive.

34. A composite bone graft, comprising:

a first bone portion;  
a second bone portion provided on said first bone portion to form a graft unit; and one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

35. A composite bone graft, comprising: a plurality of cortical bone portions layered to form a graft unit, and one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

36. A composite bone graft, comprising:

one or more cortical bone portions layered to form a first unit;  
one or more cortical bone portions layered to form a second unit;  
one or more cancellous bone portions layered to form a third unit; said third unit disposed between said first unit and said second unit to form a graft unit; and one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

37. A composite bone graft, comprising:

a graft unit having one or more through-holes configured to accommodate one or more pins, said graft unit comprising:  
two or more bone portions layered to form said graft unit, and one or more pins connecting bone portions of said graft unit, said composite bone graft does not comprise an adhesive.

38. The composite bone graft of claim 37, said one or more pins comprising one or more biocompatible materials selected from the group consisting of: cortical bone; stainless steel; titanium; cobalt-chromium molybdenum alloy; a plastic of one or more members selected from the group consisting of: nylon, polycarbonate, polypropylene, polyacetal, polyethylene, and polysulfone; and one or more bioabsorbable polymers.

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39. The composite bone graft of claim 38, said two or more bone portions comprising:  
a first bone portion comprising one or more cortical bone portions;  
a second bone portion comprising one or more cortical bone portions; and  
a third bone portion comprising one or more cancellous bone portions disposed between said first bone portion and said second bone portion to form said graft unit.
40. The composite bone graft of claim 38, said one or more pins comprise one or more cortical bone pins.
41. A composite bone graft, comprising:  
a graft unit having one or more through-holes configured to accommodate one or more pins, said graft unit comprising:  
a first plate-like cortical bone portion;  
a second plate-like cortical bone portion;  
a plate-like cancellous bone portion disposed between said first plate-like cortical bone portion and said second plate-like cortical bone portion to form said graft unit, and  
one or more cortical bone pins connecting bone portions of said graft unit, said composite bone graft does not comprise an adhesive.
42. A composite bone graft, comprising:  
a graft unit having one or more through-holes configured to accommodate one or more pins, said graft unit comprising:  
a first plate-like bone portion;  
a second plate-like bone portion provided on said first plate-like bone to form said graft unit, and  
one or more bone pins for holding together said graft unit, said composite bone graft does not comprise an adhesive.
43. A method for restoring vertical support of the posterior column, comprising implanting a composite bone graft comprising two or more distinct-bone portions held together by one or more biocompatible connectors, at a site in a patient.
44. A composite bone graft, comprising:  
a graft unit having one or more through-holes configured to accommodate one or more pins, said graft unit comprising:  
two or more bone portions layered to form said graft unit,  
one or more pins connecting said bone portions of said graft unit, and  
a centrally located through-hole disposed perpendicular to interfaces of layered bone portions of said graft unit, said composite bone graft does not comprise an adhesive.
45. A method for making a composite bone graft for implantation into a patient, comprising:

stacking two or more parallel bone planks to form a graft unit;  
providing one or more through-holes in said graft unit perpendicular to I  
interfaces of bone planks;  
connecting said two or more parallel bone planks of said graft unit with  
one or more pins disposed in said one or more through-holes to form a pinned  
graft unit; and  
shaping said pinned graft unit to form said composite bone graft.

46. A composite bone graft, comprising:  
one or more cortical bone portions layered to form a first unit;  
one or more cortical bone portions layered to form a second unit;  
one or more demineralized cancellous bone portions layered to form a  
third unit; said third unit disposed between said first unit and said second unit to  
form a graft unit; and  
one or more biocompatible connectors for holding together said graft unit, said  
biocompatible connectors do not comprise an adhesive.

47. A composite bone-graft, comprising:  
one or more cortical bone portions layered to form a first unit;  
one or more cortical bone portions layered to form a second unit;  
one or more demineralized cortical bone portions layered to form a third  
unit; said third unit disposed between said first unit and said second unit to form a  
graft unit; and  
one or more biocompatible connectors for holding together said graft unit,  
said biocompatible connectors do not comprise an adhesive.

49. A composite bone graft, comprising:  
a first unit comprising one or more bone portions;  
a second unit connected to said first unit, comprising one or more bone  
portions; and  
one or more biocompatible connectors for connecting said first unit and said  
second unit, wherein said first unit and said second unit are not in physical contact  
and define a void therebetween, said biocompatible connectors do not comprise  
an adhesive.

50. A composite bone graft, comprising: two or more distinct interlocking cortical  
bone portions.

51. A composite bone graft, comprising: two or more distinct adjacent bone portions  
where adjacent bone portions are configured to interlock with each other.

52. A composite bone graft, comprising: two or more distinct adjacent bone portions  
where adjacent bone portions are configured to interlock with each other, and one  
or more locking pins partially or entirely traversing a dimension of said composite  
bone graft.

- 1 53. A composite bone graft, comprising: two or more distinct adjacent bone portions  
2 where adjacent bone portions are configured to interlock with each other to form  
3 an interlocked graft unit, said interlocked graft unit is self-locking.  
1
- 1 54. A composite bone graft, comprising: two or more distinct adjacent bone portions,  
2 said distinct adjacent bone portions comprising complementary peg-like  
3 protrusions and corresponding depressions, said protrusions and depressions  
4 interlock to provide an interlocking fit between said adjacent bone portions.  
1
- 1 55. A composite bone graft, consisting essentially of: two or more distinct adjacent  
2 bone portions where adjacent bone portions are configured to interlock with each  
3 other.  
1
- 1 56. A composite bone graft, consisting essentially of: two or more distinct adjacent  
2 bone portions, said distinct adjacent bone portions comprising complementary  
3 peg-like protrusions and corresponding depressions, said protrusions and  
4 depressions interlock to provide an interlocking fit between said adjacent bone  
5 portions.  
1
- 1 57. A composite bone graft, consisting essentially of: two or more distinct adjacent  
2 bone portions, said distinct adjacent bone portions comprising complementary  
3 peg-like protrusions and corresponding depressions, said protrusions and  
4 depressions interlock to provide an interlocking fit between said adjacent bone  
5 portions; and one or more locking pins partially or entirely traversing a  
6 dimension of said composite bone graft.  
1
- 1 58. A composite bone graft, consisting essentially of: two or more distinct adjacent  
2 bone portions where adjacent bone portions are configured to interlock with each  
3 other, and one or more locking pins partially or entirely traversing a dimension of  
4 said composite bone graft.  
1
- 1 59. A composite bone graft, comprising: two or more distinct adjacent bone portions  
2 where adjacent bone portions are configured to interlock with each other to form  
3 an interlocked graft unit, and one or more locking pins traversing a dimension of  
4 said composite bone graft, to lock said interlocked graft unit.  
1
- 1 60. A composite bone graft, comprising: two or more distinct interlocking bone  
2 portions, said interlocking bone portions are self-locking.  
1
- 1 61. A composite bone graft, comprising: two or more distinct interlocking bone  
2 portions, and one or more locking pins to lock said interlocking bone portions.  
1

ABSTRACT OF THE DISCLOSURE

This invention provides a method for manufacture of autograft, allograft and xenograft implants which comprises assembling such implants from smaller pieces of graft  
5 materials to form a larger graft implant product.

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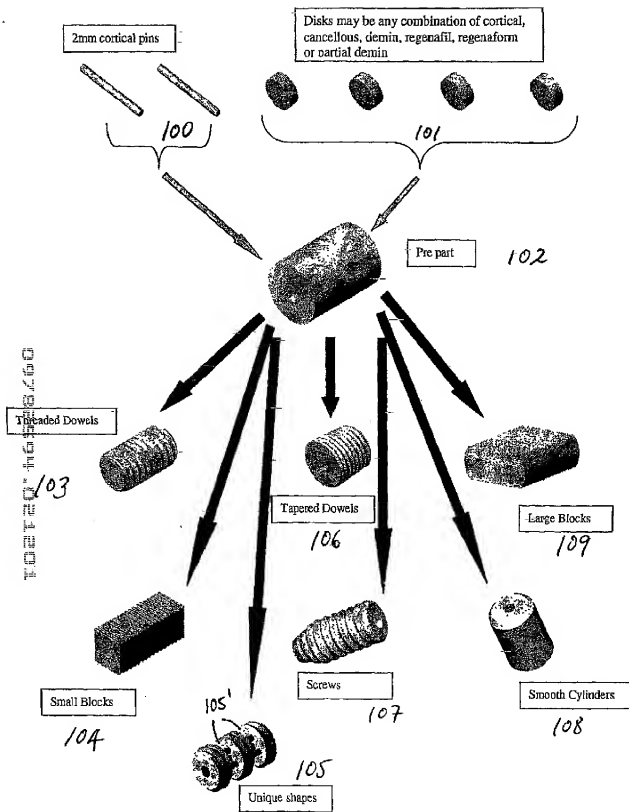
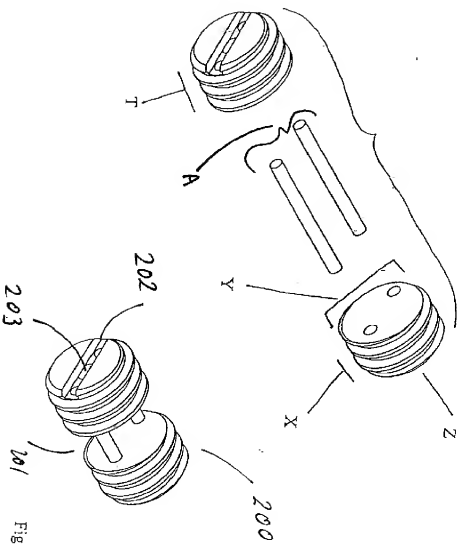


Figure 1



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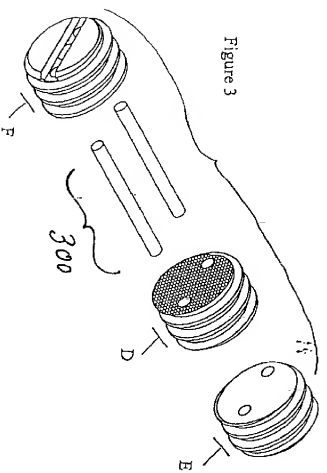


Figure 3

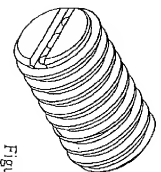


Figure 4

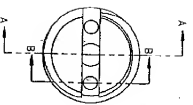


Figure 5

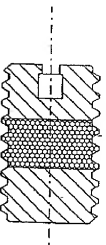


Figure 6

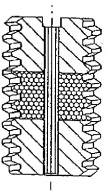


Figure 7

Figure 8

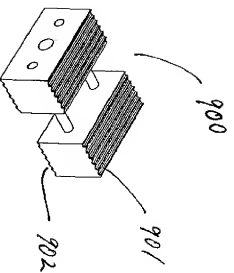
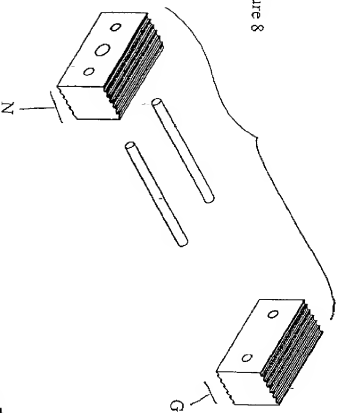


Figure 9

Figure 10

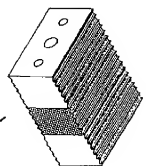
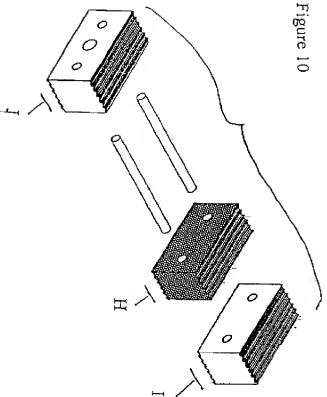


Figure 11

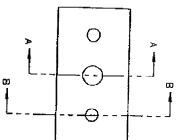


Figure 12

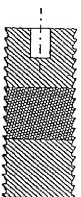


Figure 13

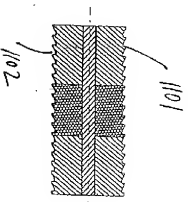


Figure 14

Figure 15

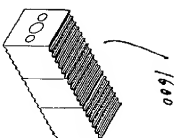
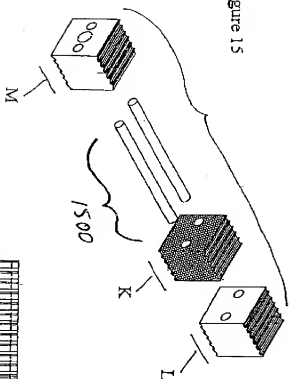


Figure 16

Figure 17

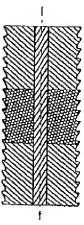


Figure 18

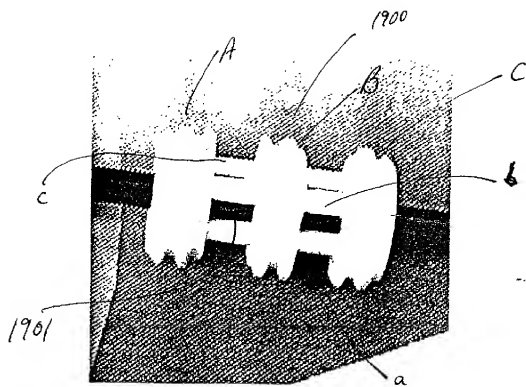
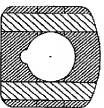
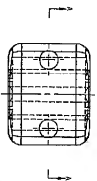
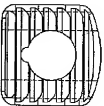


FIGURE 19



SECTION A-A  
SCALE 8:1



DETAIL B  
SCALE 8:1

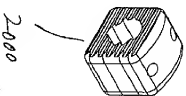
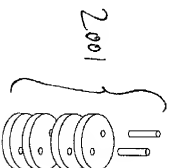
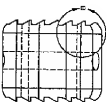
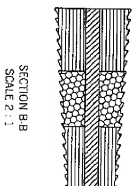
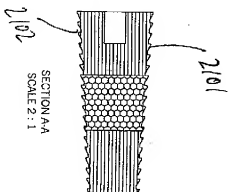
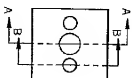
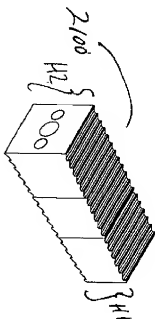
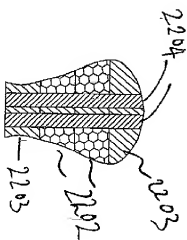
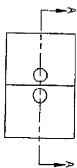


Figure 20  
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Figure 21



SECTION AA  
SCALE 2:1

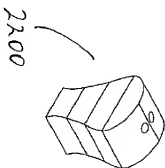
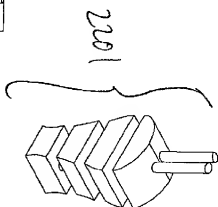
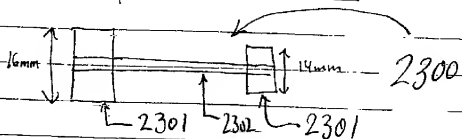
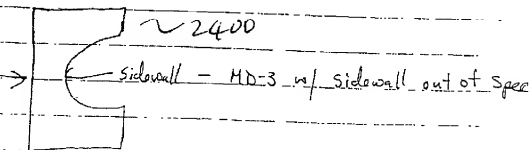


Figure 23

Create a tapered dowel



Salvage dowel out of Spec



Solution - Create an MD-2

Figure 24A

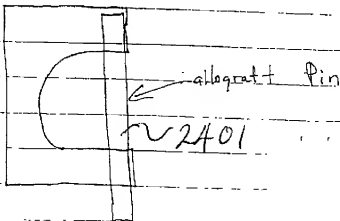
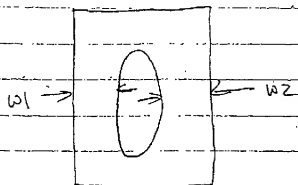


Figure 24B

Figure 24

Figure 25



MD-2 out of spec @ sidewall

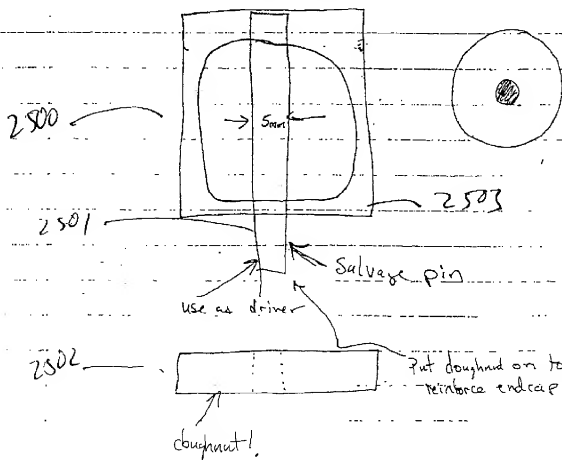
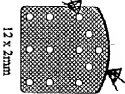


Figure 26

Cancellous bone

2600L



12 x 2mm



6 x 2mm



9 x 3mm



12 x 3mm

Cortical Pins 100



6 x 3mm



6 x 4mm

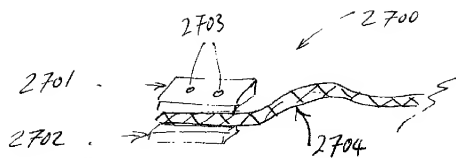


Figure 27

09782594-021201

# **PATENT APPLICATION**

**DECLARATION AND POWER OF ATTORNEY  
FOR PATENT APPLICATION**

**ATTORNEY DOCKET NO. RTI-112R**

As a below named inventor, I hereby declare that:

My residence/post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**ASSEMBLED IMPLANT**

the specification of which is attached hereto unless the following box is checked:

( ) was filed on \_\_\_\_\_ as US Application Serial No. or PCT International Application  
Number \_\_\_\_\_ and was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR 1.56.

**Foreign Application(s) and/or Claim of Foreign Priority**

I hereby claim foreign priority benefits under Title 35, United States Code Section 119 of any foreign application(s) for patent or inventor(s) certificate listed below and have also identified below any foreign application for patent or inventor(s) certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE FILED	PRIORITY CLAIMED UNDER 35 U.S.C. 119
			YES: _____ NO: _____
			YES: _____ NO: _____

**Provisional Application**

I hereby claim the benefit under Title 35, United States Code Section 119(e) of any United States provisional application(s) listed below:

APPLICATION SERIAL NUMBER	FILING DATE
60/181,622	2/10/2000

**U.S. Priority Claim**

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

APPLICATION SERIAL NUMBER	FILING DATE	STATUS(patented/pending/abandoned)
60/181,622	2/10/2001	Pending
09/191,132	11/13/1998	Pending
09/378,527	8/20/1999	Pending
09/370,194	9/7/1999	Pending
29/123,227	5/12/2000	Pending

**POWER OF ATTORNEY:**

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) listed below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Gerard H. Bencen, Reg. No. 35746

Timothy H. Van Dyke, Reg. No. 43218

Send Correspondence to:  
Gerard H. Bencen,  
Bencen & Van Dyke, P.A.  
1630 Hillcrest Street  
Orlando, Florida 32803

Direct Telephone Calls To:  
Gerard H. Bencen  
407-228-0328

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Inventor: John R. Bianchi

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature \_\_\_\_\_

Date \_\_\_\_\_

DECLARATION AND POWER OF ATTORNEY  
FOR PATENT APPLICATION (continued)

ATTORNEY DOCKET NO. RTL-112R

Full Name of Inventor: C. Randal Mills

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature

Date

Full Name of Inventor: P.J. Gerham

Citizenship: \_\_\_\_\_

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature

Date

Full Name of Inventor: Michael Esch

Citizenship: \_\_\_\_\_

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature

Date

Full Name of Inventor: Kevin C. Carter

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same

Inventor's Signature

Date

Full Name of Inventor: Pat Coleman

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same

Inventor's Signature

Date

Full Name of Inventor: Kevin Ross

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same

Inventor's Signature

Date

DECLARATION AND POWER OF ATTORNEY  
FOR PATENT APPLICATION (continued)

ATTORNEY DOCKET NO. RTL-112R

Full Name of Inventor: Harry W. Rambo

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same

Inventor's Signature

Date

Full Name of Inventor: Darren G. Jones

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same

Inventor's Signature

Date

Full Name of Inventor: Davna Busldrk

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same

Inventor's Signature

Date

## **EXHIBIT 2**



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R

CONFIRMATION NO. 9490

## FORMALITIES LETTER



\*000000005876712\*

Gerard H. Bencen  
Bencen & Van Dyke, P. A.  
1630 Hillcrest Street  
Orlando, FL 32803

Date Mailed: 03/19/2001

## NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

## Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.  
*Applicant must submit \$ 710 to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).*
- Total additional claim fee(s) for this application is \$3618.
  - \$738 for 41 total claims over 20.
  - \$2880 for 36 independent claims over 3 .
- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.18(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- The balance due by applicant is \$ 4458.

The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Substitute drawings in compliance with 37 CFR 1.84 because:
  - drawing sheets do not have the appropriate margin(s) (see 37 CFR 1.84(g)). Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. ( 5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch);

---

*A copy of this notice **MUST** be returned with the reply.*

*EW*  
\_\_\_\_\_  
Customer Service Center  
Initial Patent Examination Division (703) 308-1202  
PART 3 - OFFICE COPY



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20535  
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R

05/31/2001 ROSHAN1 00000040 09782594

CONFIRMATION NO. 9490

Gerard H. Bencen 01 FC:101 710.00 OP  
Bencen & Van Dyke, P. A. 02 FC:102 2880.00 OP  
1630 Hillcrest Street 03 FC:103 738.00 OP  
Orlando, FL 32803 04 FC:105 130.00 OP

## FORMALITIES LETTER



\*0000000005876712\*

Date Mailed: 03/19/2001

## NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

## Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.  
*Applicant must submit \$ 710 to complete the basic filing fee and/or file a small-entity statement claiming such status (37 CFR 1.27).*
- Total additional claim fee(s) for this application is \$3618.
  - \$738 for 41 total claims over 20.
  - \$2880 for 36 independent claims over 3.
- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- The balance due by applicant is \$ 4458.

The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Substitute drawings in compliance with 37 CFR 1.84 because:
  - drawing sheets do not have the appropriate margin(s) (see 37 CFR 1.84(g)). Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. (5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch);

## **EXHIBIT 3**



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Bianchi *et al.*

Application No.: 09/782,594

Filed: 2/12/2001

Title: ASSEMBLED IMPLANT

Attorney Docket No.: RTI-112R

Group Art Unit:  
1615

**RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION**

Assistant Commissioner for Patents  
Washington, D.C. 20231  
Attention: Box Missing Parts

Sir:

This is in response to a Notice to File Missing Parts of Application under 37 CFR 1.53(f). Enclosed is a copy of said Notice and the following documents and fees to complete the filing requirements of the above-identified application.

(X) Executed Declaration and Power of Attorney. The above-identified application is the same application which the inventor executed by signing the enclosed declaration.

(X) Statutory basic filing fee of \$710.00. (X) Utility ( ) Design

(X) Additional claim fees of \$3,618.00 (\$738.00 for 41 total claims over 20 and \$2,880.00 for 36 independent claims over 3).

(X) Missing Parts Surcharge of \$130.00.

(X) New formal drawings pursuant to Notice to File Missing Parts of Application.


I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope with sufficient postage addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit: 5/21/2001

Typed Name: Gerard H. Bencen

Respectfully submitted,

By

  
Gerard H. Bencen, Reg. No. 35746

Signature: 

Date: 5/21/2001

Telephone No.: 407-228-0328

---

*A copy of this notice **MUST** be returned with the reply.*

---

Customer Service Center

Initial Patent Examination Division (703) 308-1202

**PART 2 - COPY TO BE RETURNED WITH RESPONSE**

105250" 46528760

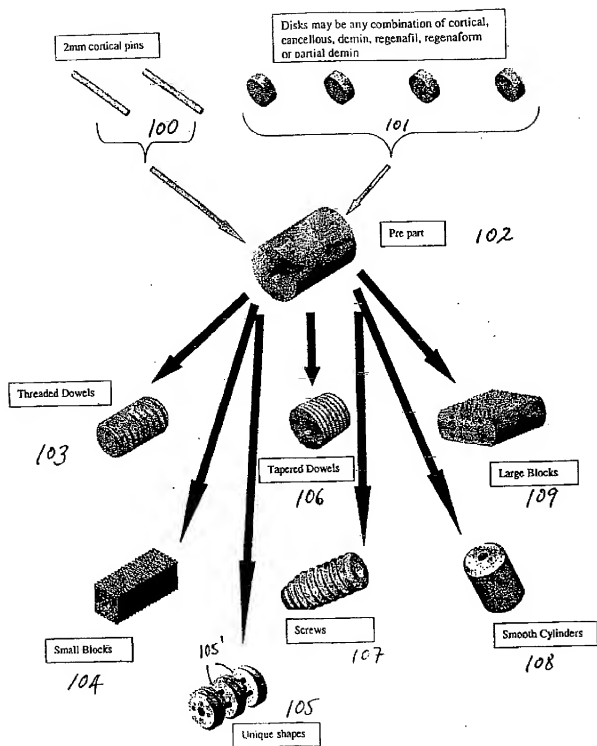


Figure 1

105250\*46528760

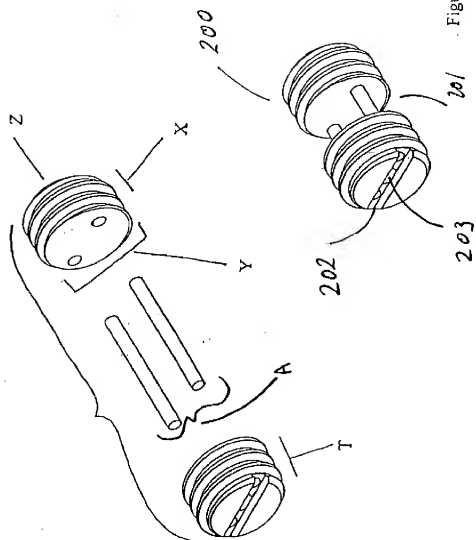


Figure 2

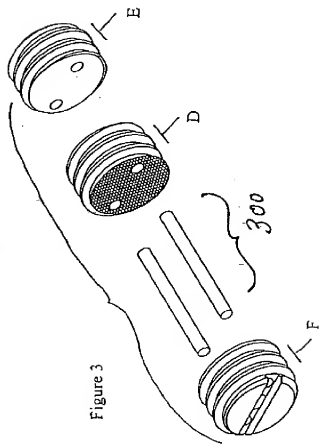


Figure 3

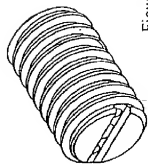


Figure 4

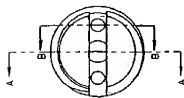


Figure 5

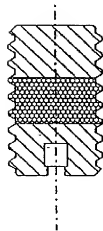


Figure 6

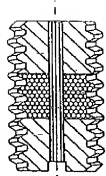


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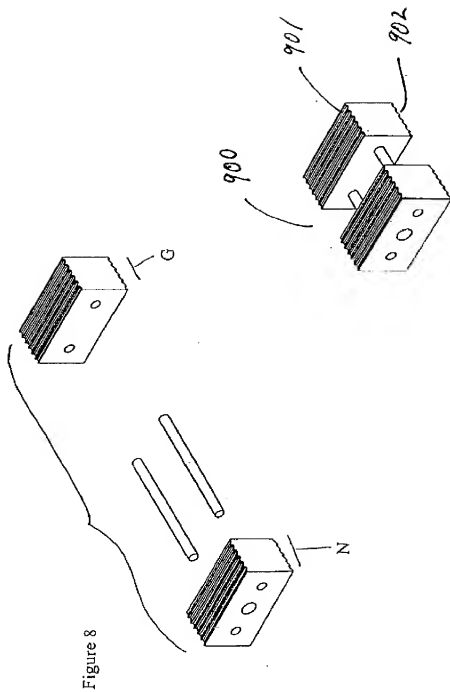


Figure 9

Figure 10

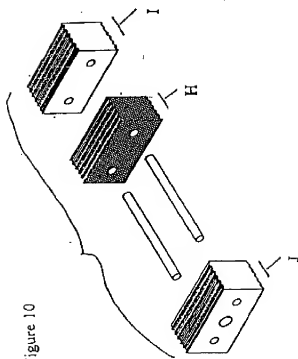


Figure 11

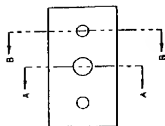
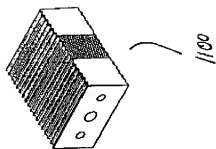


Figure 12

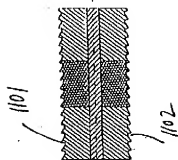


Figure 13

Figure 14

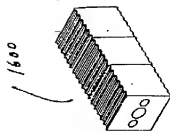


Figure 16

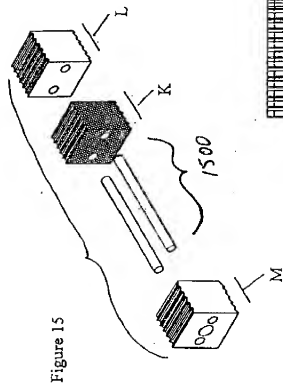


Figure 15

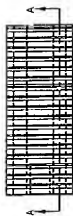


Figure 17

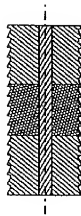
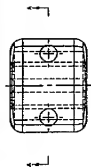


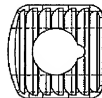
Figure 18



09782594.052501



SECTION A-A  
SCALE 4:1



DETAIL B  
SCALE 8:1

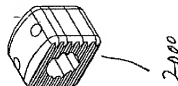
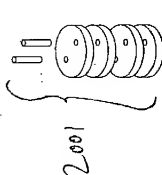
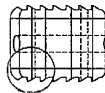


Figure 20

105250" 46528260

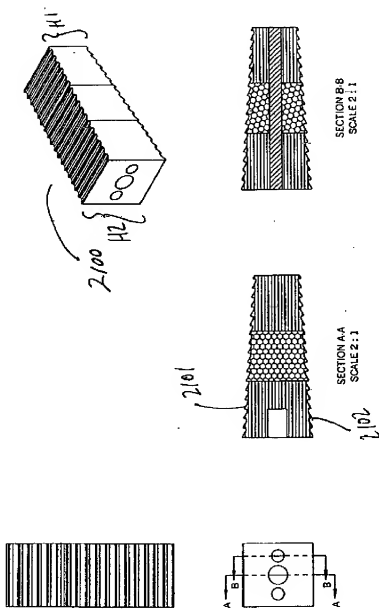
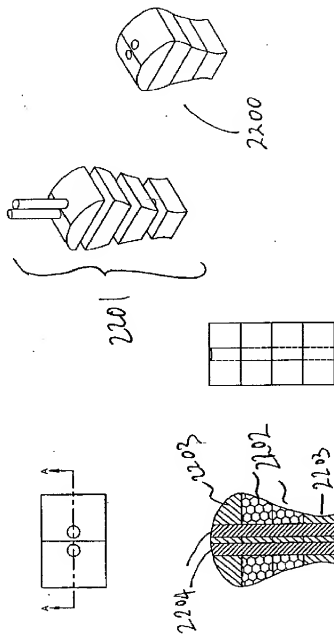


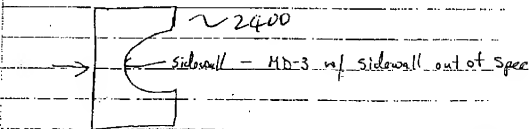
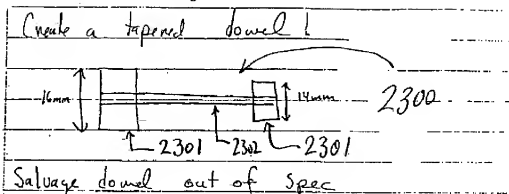
Figure 21



SECTION A-A  
SCALE 2:1

Figure 22

Figure 23



Solution - create an MD-2 Figure 24A

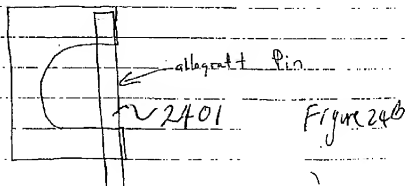
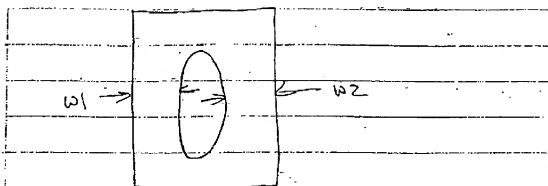
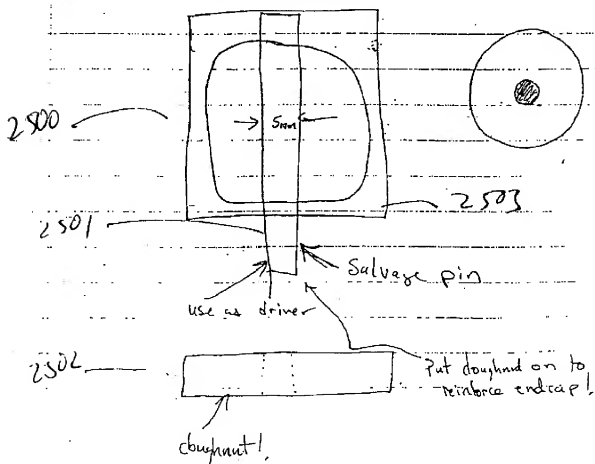


Figure 24

Figure 25



MD-2 out of spec @ Side wall



09782594.052501

09782594.052501

Figure 26

Cartilious bone

2600✓



12 x 20mm



6 x 20mm



9 x 30mm



12 x 30mm



6 x 30mm



6 x 40mm

Cartil Pins 100

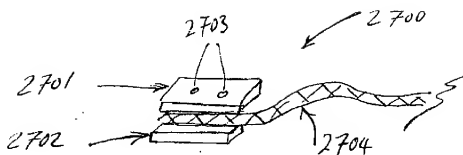


Figure 27

# PATENT APPLICATION

## DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

ATTORNEY DOCKET NO. RTI-112R

As a below named inventor, I hereby declare that:

My residence/post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**ASSEMBLED IMPLANT**

the specification of which is attached hereto unless the following box is checked:

☐ was filed on \_\_\_\_\_ as US Application Serial No. or PCT International Application

Number \_\_\_\_\_ and was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose all information which is material to patentability as defined in 37

### Foreign Application(s) and/or Claim of Foreign Priority

I hereby claim foreign priority benefits under Title 35, United States Code Section 119 of any foreign application(s) for patent or inventor(s) certificate listed below and have also identified below any foreign application for patent or inventor(s) certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE FILED	PRIORITY CLAIMED UNDER 35 U.S.C. 119
			YES: _____ NO: _____
			YES: _____ NO: _____

### Provisional Application

I hereby claim the benefit under Title 35, United States Code Section 119(e) of any United States provisional application(s) listed below:

APPLICATION SERIAL NUMBER	FILING DATE
60/181,622	2/10/2000

### U.S. Priority Claim

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NUMBER	FILING DATE	STATUS(patented/pending/abandoned)
60/181,622	2/10/2001	Pending
09/191,132	11/13/1998	Pending
09/378,527	8/20/1999	Pending
09/370,194	9/7/1999	Pending
29/123,227	5/12/2000	Pending

### POWER OF ATTORNEY:

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) listed below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Gerard H. Bencen, Reg. No. 35746

Timothy H. Van Dyke, Reg. No. 43218

Send Correspondence to:  
Gerard H. Bencen  
Bencen & Van Dyke, P.A.  
1630 Hillcrest Street  
Orlando, Florida 32803

Direct Telephone Calls To:  
Gerard H. Bencen  
407-228-0328

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Inventor: John R. Bianchi

Citizenship: USA

Residence: Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature

Date

DECLARATION AND POWER OF ATTORNEY  
FOR PATENT APPLICATION (continued)

FORNEY DOCKET NO. RTL-112R

Full Name of Inventor: C. Randa Mills Citizenship: USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature: [Signature] Date: 02/23/01

Full Name of Inventor: P.J. Gorham Citizenship: \_\_\_\_\_

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature: [Signature] Date: 2/20/01

Full Name of Inventor: Michael Esch Citizenship: \_\_\_\_\_

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature: [Signature] Date: 3/7/01

Full Name of Inventor: Kevin C. Carter Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same

Inventor's Signature: [Signature] Date: 2/22/01

Full Name of Inventor: Pat Coleman Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same

Inventor's Signature: [Signature] Date: 3/20/01

Full Name of Inventor: Kevin Ross Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same

Inventor's Signature: [Signature] Date: 3/8/01

**DECLARATION AND POWER OF ATTORNEY  
FOR PATENT APPLICATION (continued)**

**ATTORNEY DOCKET NO. RTL-112R**

Full Name of Inventor: Harry W. Rambo

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same



Inventor's Signature

03/13/01

Date

Full Name of Inventor: Darren G. Jones

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same



Inventor's Signature

2/20/01

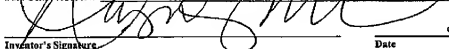
Date

Full Name of Inventor: Dayna Buskirk

Citizenship: USA

Residence: 1 Innovation Drive, Alachua, FL 32615

Post Office Address: Same



Inventor's Signature

2/23/01

Date

## **EXHIBIT 4**

#6  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Bianchi *et al.*

Application No.: 09/782,594

Filed: 2/12/2001

Title: ASSEMBLED IMPLANTS



Group Art Unit: 1615

Attorney Docket No.: RTI-112R

Assistant Commissioner  
for Patents  
Washington, D.C. 20231

1615  
JUL 31 2001  
TECH CENTER 1600/2900

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SUBMISSION OF NEW FORMAL DRAWINGS

Dear Sir:

Applicants request that the drawings provided herein replace the previously submitted drawings which accompanied Applicants' response filed on May 21, 2001, to a Notice to File Missing Parts of the Application. Although Applicants fully complied with the requisite set forth in the Notice, Applicants would prefer to use the enclosed new drawings as they believe them to be more aesthetically pleasing. Applicants assert that the new formal drawings do not contain any new subject matter.

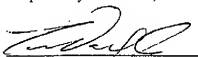
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope with sufficient postage addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit: 7-23-2001

Typed Name: Timothy H. Van Dyke

Signature: 

Respectfully Submitted,



Timothy H. Van Dyke  
Reg. No. 43218  
Bencen & Van Dyke, P.A.  
1630 Hillcrest Street  
Orlando, Florida 32803  
Telephone: 407-228-0328

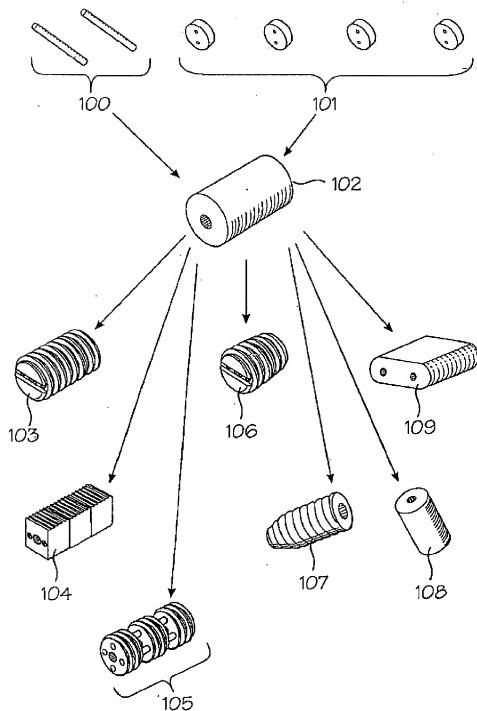
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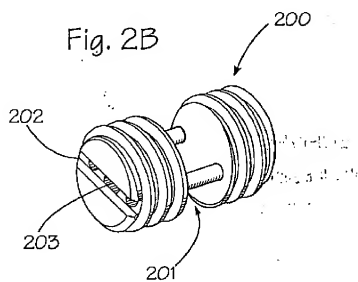
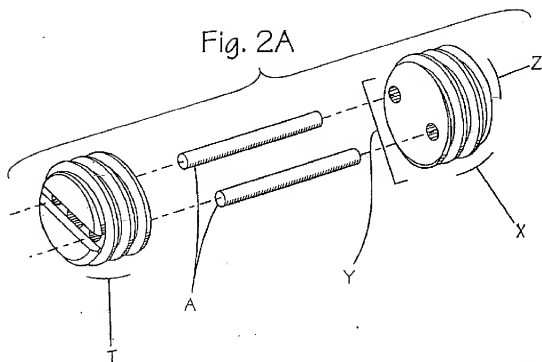
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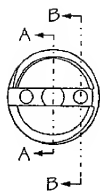
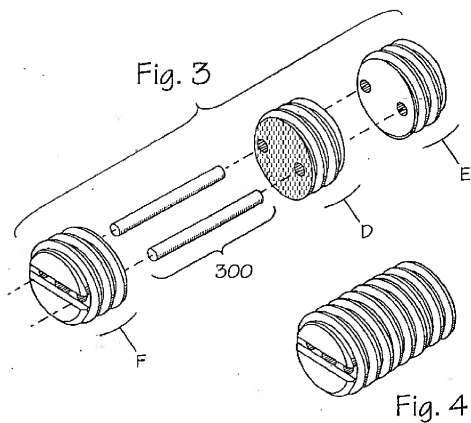


Fig. 5

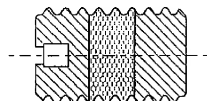


Fig. 6

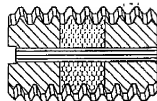
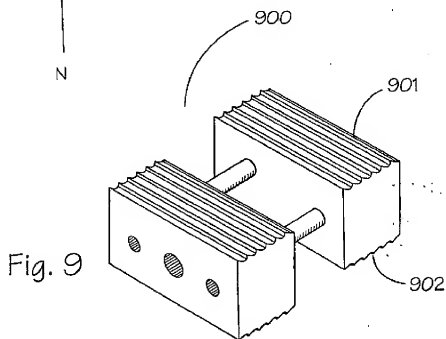
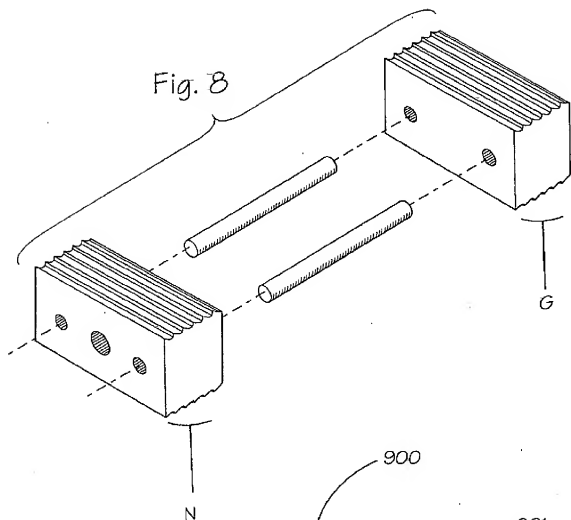


Fig. 7



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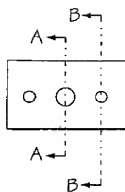
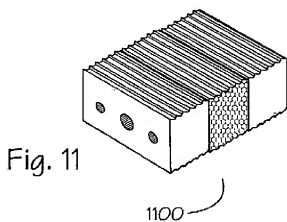
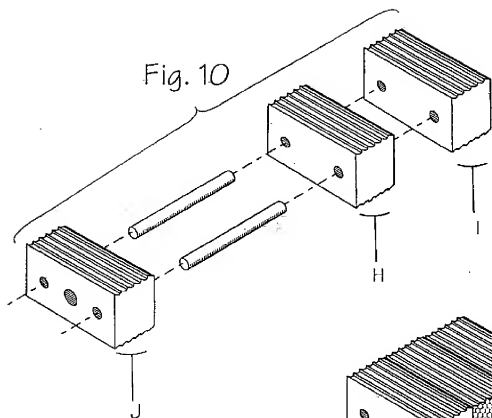


Fig. 12

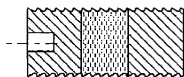


Fig. 13

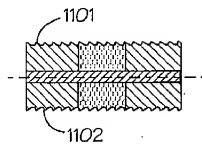
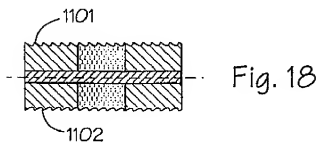
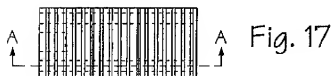
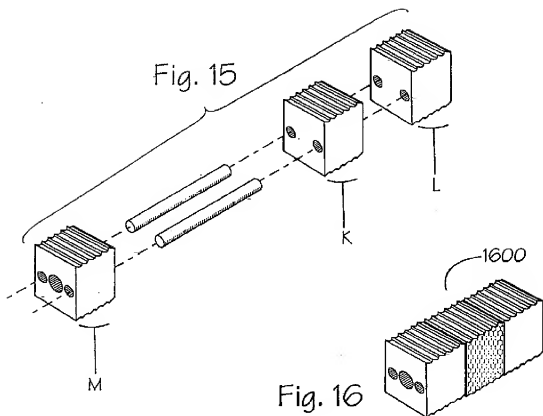


Fig. 14

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Fig. 19A

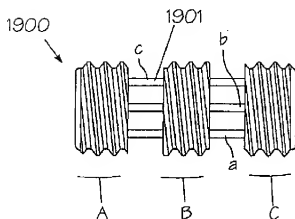
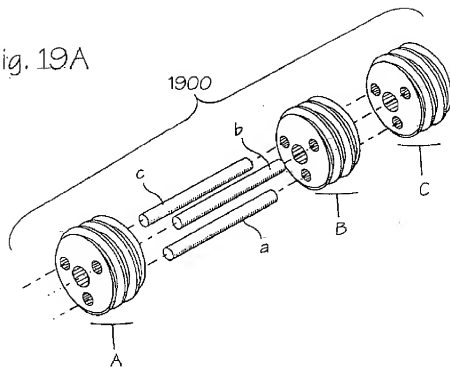


Fig. 19B

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Fig. 20A

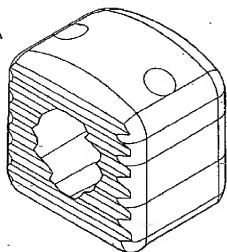


Fig. 20B

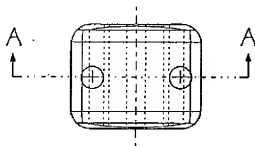


Fig. 20C

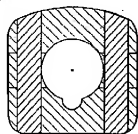


Fig. 20D

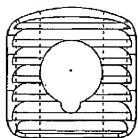


Fig. 20E

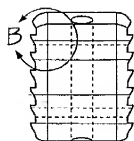


Fig. 20F

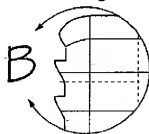


Fig. 20G



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Fig. 21A

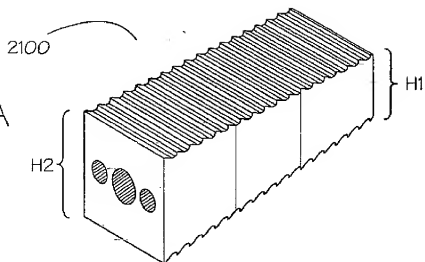


Fig. 21B

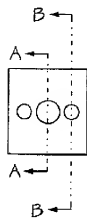


Fig. 21C

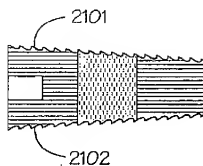


Fig. 21D

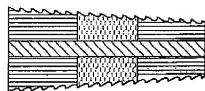
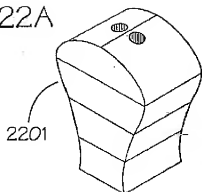


Fig. 21E

Fig. 22A



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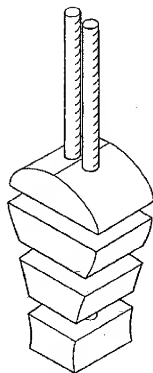


Fig. 22C

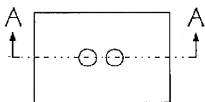


Fig. 22B

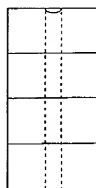
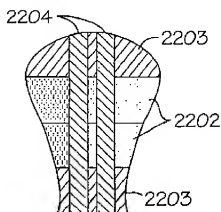


Fig. 22D

Fig. 22E

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Fig. 23

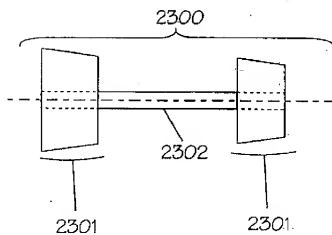


Fig. 24A

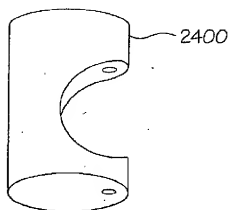
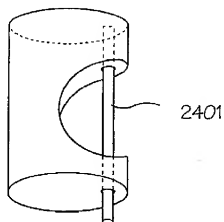


Fig. 24B



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Fig. 25A

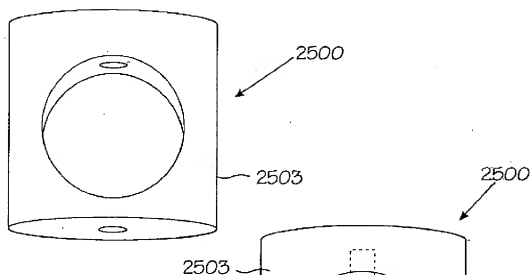
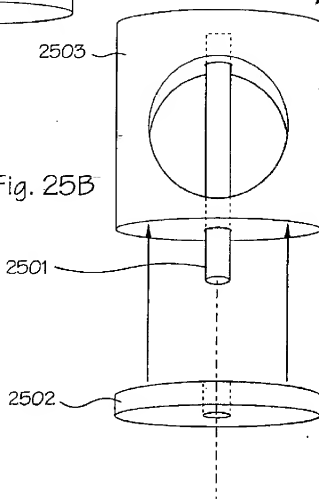


Fig. 25B



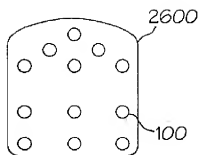


Fig. 26A

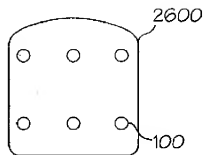


Fig. 26B

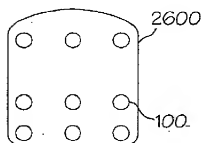


Fig. 26C

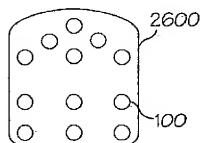


Fig. 26D

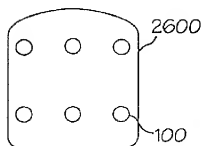


Fig. 26E

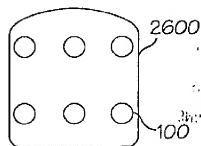


Fig. 26F

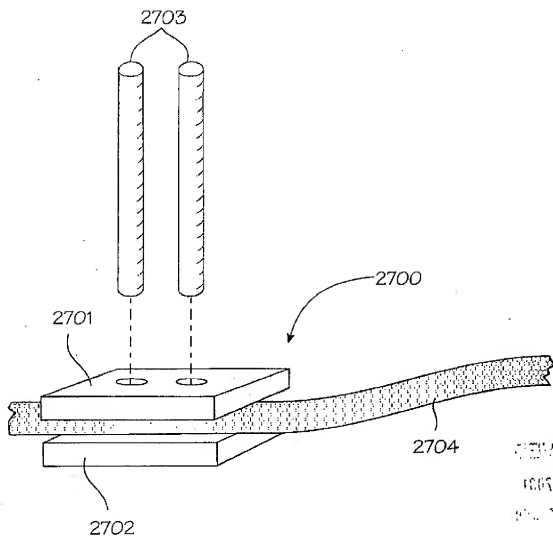
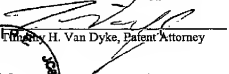
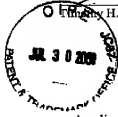


Fig. 27

## **EXHIBIT 5**

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Assistant Commissioner for Patents  
Washington, D.C. 20231-en 7-25-2001

  
Timothy H. Van Dyke, Patent Attorney



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Bianchi *et al.*  
Application No: 09/782,594  
Filed: 2/12/2001  
Title: ASSEMBLED IMPLANT  
Docket No: RTI-112R

To: Assistant Commissioner for Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT UNDER 37 CFR 1.115

Dear Sir:

Please amend this application as follows:

In the claims:

Please cancel claims 1-25, without prejudice.

Remarks

Claims 1-25 have been cancelled without prejudice. Applicants reserve the right to pursue any subject matter affected by this cancellation in copending or later filed divisional or continuation applications. Reconsideration and further examination is

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respectfully requested. Applicants assert that all pending claims are in condition for allowance, and such action is respectfully requested.

The Examiner is invited to call the undersigned if clarification is needed on any aspect of this Preliminary Amendment, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

---

Timothy H. Van Dyke  
Patent Attorney, Reg. No. 43,218  
Address: Bencen & Van Dyke, P.A.  
1630 Hillcrest Street  
Orlando, FL 32803  
Phone No: 407-228-0328  
Fax No: 407-228-0329

## **EXHIBIT 6**



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address COMMISSIONER FOR PATENTS  
P.O. Box 1459  
Alexandria, Virginia 22313-1459  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490

7590

07/31/2003

DONALD J. POCHOPIEN  
McANDREWS, HELD & MALLOY, LTD.  
CITICORP CENTER, 34TH FLOOR  
500 WEST MADISON STREET  
CHICAGO, IL 60661

EXAMINER

AZPURI, CARLOS A

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/31/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/782,594

Applicant(s)

BIANCHI ET AL.

Examiner

Carlos A. Azpuru

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.135(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 6-18, 21-23, drawn to a method of manufacturing an allograft, autograft or xenograft, classified in class 128, subclass 1+.
- II. Claim 2, 24, and 25 drawn to a kit comprising an assemblable autograft, allograft, or xenograft and assembled implant, classified in class 623, subclass 1+.
- III. Claims 3-5, drawn to a method of strengthening an autograft, classified in class 623, subclass 1+.
- IV. Claims 19 and 20, drawn to a method of repairing bone, classified in class 623, subclass 1+.
- V. Claims 26-42, 44, 45, and 46-51, drawn to a composite bone graft and method of making, classified in class 623, subclass 11.11+.
- VI. Claim 43, drawn to a method of restoring vertical support, classified in class 623, subclass 11.11+.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made

by another materially different process such as by a single piece manufacturing process.

Inventions Group I and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions.

Inventions Group I and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions.

Inventions Group I and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different effects.

Inventions Group I and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Donald J. Pochopien on July 15, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

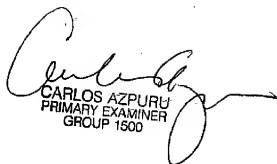
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Application/Control Number: 09/782,594  
Art Unit: 1615

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Ca  
July 15, 2003



CARLOS AZPURU  
PRIMARY EXAMINER  
GROUP 1500

## **EXHIBIT 7**

ATTORNEY DOCKET NO. RT1 112R /1915-13980/US02

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:

Blanchi, John R., et al.

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

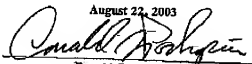
Group Art Unit: 1615

Examiner: Carlos A. Azpuru

## CERTIFICATE OF FACSIMILE

I hereby certify that this correspondence is being sent by facsimile to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, to the attention of Examiner Azpuru at facsimile telephone number 1-703-872-9307 on this date:

August 22, 2003

Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants

## RESPONSE TO RESTRICTION UNDER 35 U.S.C. § 121

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

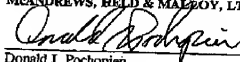
Sir:

In response to the restriction requirement sent via facsimile, and requesting an election of invention, the Applicants hereby elect to prosecute the invention of Group V (claims 26-42, 44-61) directed to a composite bone graft and method of making.

Respectfully submitted,

McANDREWS, HELD &amp; MALLOY, LTD.

By:

Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8133

FAX RECEIVED

AUG 25 2003

GROUP 1600

Date: August 22, 2003

J:\open\Dipl\Regeneration Technologies\USPTO\13980\US02\Election of Invention.doc



McANDREWS, HELD & MALLOY  
34TH FLOOR  
500 WEST MADISON STREET  
CHICAGO, ILLINOIS 60661

TELEPHONE: (312) 775-8000

FACSIMILE: (312) 775-8100

**FAX COVER LETTER****CONFIDENTIAL**

THE ENCLOSED MATERIAL IS INTENDED FOR THE RECIPIENT NAMED BELOW AND, UNLESS OTHERWISE EXPRESSLY INDICATED, IS CONFIDENTIAL AND PRIVILEGED INFORMATION. ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THE ENCLOSED MATERIALS IS PROHIBITED. IF YOU RECEIVE THIS TRANSMISSION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE, AT OUR EXPENSE, AND DESTROY THE ENCLOSED MATERIALS. YOUR COOPERATION IS APPRECIATED.

TO:	United States Patent and Trademark Office	
FROM:	Donald J. Pochopiën	USER ID:8090
DATE:	August 22, 2003	
FAX NO.:	703/872-8307	
CLIENT:	1915	
MATTER:	13980US02	

Number of Pages This Transmission (Including Cover Page): 2

Message:

If you have problems receiving this facsimile transmission, please contact the sender at the above telephone number.

**FAX RECEIVED****AUG 25 2003  
GROUP 1600****OFFICIAL**

## **EXHIBIT 8**



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490

7590 11/04/2003  
DONALD J. POCHOPIEN  
McANDREWS, HELD & MALLOY, LTD.  
CITICORP CENTER, 34TH-FLOOR  
500 WEST MADISON STREET  
CHICAGO, IL 60661

EXAMINER	
FRESHILIC, PAUL B	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 11/04/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/782,594

Examiner

Paul B. Prebille

Applicant(s)

BIANCHI ET AL.

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-25, 43 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-42, 44 and 46-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Specification***

The disclosure is objected to because of the following informalities:

Upon review of the pending claims it was determined that there was no claim 48. Therefore, the Examiner renumbered claims 49-61 as claims 48-60, respectively so that the claims were consecutively ordered. Applicants are respectfully requested to renumber their claim set accordingly.

Appropriate correction is required.

***Election/Restrictions***

Claims 1-25 and 43 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 23 filed August 25, 2003.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Va. Claims 26-42, 44, and 46-60, drawn to the composite bone graft, classified in class 623, subclass 23.51.
- Vb. Claim 45, drawn to method of making a composite bone graft, classified in class 264, subclass 405.

The inventions are distinct, each from the other because of the following reasons:

Inventions Va and Vb are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case, the product as claimed could be made by a different process such as shaping the component parts prior to assembling them into a unit.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Donald Pochopien on October 29, 2003 a provisional election was made with traverse to prosecute the invention of Group Va, claims 26-42, 44, and 46-60. Affirmation of this election must be made by applicant in replying to this Office action. Claim 45 as well as previously withdrawn claims 1-25 and 43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The drawings are objected to because in Figures 6, 7, 13, 14, 18, 20C, 21D, 21E, and 22D, the crosshatching indicates metal not bone components; see MPEP 608.02.

In addition, the formal drawings filed August 8, 2001 do not contain a legend labeling the first drawing as Figure 1.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The abstract of the disclosure is objected to because it does not adequately describe the presently claimed invention. Correction is required. See MPEP § 608.01(b).

***Information Disclosure Statement***

The information disclosure statement filed October 9, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The copies may have been lost by the USPTO so the Examiner retrieved and reviewed all but one document; see page 2 of the enclosed copy of the PTO-1449. Applicants are respectfully requested to provide a copy thereof in response to this office action; i.e. a copy of the GIE et al (article).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38, 41, 42, and 53-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 38, the Markush listing is confusing and unclear because of the multiple ands and ors. It is not clear where the listing ends.

With regard to claim 41, lines 4-7, the terminology "plate-like" is considered to be indefinite because it is not clear what would fall within the scope thereof.

With regard to claim 42, "plate-like" is also used in this claim and is indefinite for the reasons that claim 41 was said to be indefinite.

With regard to claims 53-55, line 2, the term "peg-like" is considered to be indefinite because it is not clear what falls within the scope thereof.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-42, 44, and 46-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (US 6,200,347). Anderson anticipates the claim language where the bone portions as claimed are the bone grafts (16 and 17 of Figure 7 or elements 2 and 4 of Figure 1) and the pins of Anderson are threaded and do not contain adhesive (see column 5, lines 43-50); see also column 19, line 62 to column 20, line 36 and column 5, lines 1-8.

With regard to claims 50 and 51, Applicants are directed to see Figures 41 and 42C as well as column 26, line 17 et seq.

Claims 26-31, 33-35, 37, 38, 40, 42, 49, 50, 53-55, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Yaccarino, III (US 6,025,538). Yaccarino anticipates the claim language where the first portion as claimed is the first bone member (22) of Yaccarino (see Figure 6 and column 4, line 35 to column 5, line 47 as well as column 7, lines 1-10). The second bone portion as claimed is the second bone member (24) of Yaccarino.

With regard to claim 31, the third bone portion is one of the pins and the connector is the other pin; see Figure 8.

With regard to claims 49, 50, 53, and 54, the pins of Yaccarino provide the interlocking required by these claims.

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic  
Primary Examiner  
Art Unit 3738

**Notice of References Cited**

Application/Control No.

09/782,594

Applicant(s)/Patent Under  
Reexamination  
BIANCHI ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-8,554,863	04-2003	Paul et al.	623/17.11
	B	US-8,494,883	12-2002	Ferree, Bret A.	606/61
	C	US-5,084,051	01-1992	Tormala et al.	606/77
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

5

### NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

The drawing(s) filed (insert date) 7/25/01 are:

- A. ☐ approved by the Draftsperson under 37 CFR 1.84 or 1.152.  
B. ☒ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. Corrected drawings are required.

**1. DRAWINGS.** 37 CFR 1.84(a): Acceptable categories of drawings: Black ink or Color (3 sets required).

Color drawings are not acceptable until petition is granted. Fig(s) \_\_\_\_\_

Pencil and non black ink not permitted. Fig(s) \_\_\_\_\_

**2. PHOTOGRAPHS.** 37 CFR 1.84(b)

One (1) full-tone set is required. Fig(s) \_\_\_\_\_

Photographs may not be mounted. 37 CFR 1.84(e)

Photographs must meet paper size requirements of 37 CFR 1.84(f). Fig(s) \_\_\_\_\_

Poor quality (half-tone). Fig(s) \_\_\_\_\_

**3. TYPE OF PAPER.** 37 CFR 1.84(e)

Paper not flexible, strong, white, and durable.

Fig(s) \_\_\_\_\_

Erasures, alterations, overwritings, interlineations, folds, copy machine marks not accepted.

Fig(s) \_\_\_\_\_

**4. SIZE OF PAPER.** 37 CFR 1.84(f): Acceptable sizes:

21.0 cm by 29.7 cm (DIN size A4) or

21.6 cm by 27.9 cm (8 1/2 x 11 inches)

All drawing sheets not the same size.

Sheet(s) \_\_\_\_\_

Drawings sheets not an acceptable size. Fig(s) \_\_\_\_\_

**5. MARGINS.** 37 CFR 1.84(g): Acceptable margins:

Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm

Margins not acceptable. Fig(s) \_\_\_\_\_

Top (T) \_\_\_\_\_ Left (L) \_\_\_\_\_

Right (R) \_\_\_\_\_ Bottom (B) \_\_\_\_\_

**6. VIEWS.** 37 CFR 1.84(h)

REMINDER: Specification may require revision to

correspond to drawing changes, e.g., if Fig. 1 is

changed to Fig. 1A, Fig 1B and Fig. 1C, etc., the

specification, at the Brief Description of the Drawings, must likewise be changed.

Views not labeled separately or properly.

Fig(s) \_\_\_\_\_

**7. SECTIONAL VIEWS.** 37 CFR 1.84(h)(3)

Sectional designation should be noted with

Arabic or Roman numbers. Fig(s) 5, 12, 17, 20B  
21C, 22C

**8. ARRANGEMENT OF VIEWS.** 37 CFR 1.84(i)

Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) \_\_\_\_\_

**9. SCALE.** 37 CFR 1.84(j)

Scale not large enough to show mechanism

without crowding when drawing is reduced in size to two-thirds in reproduction.

Fig(s) \_\_\_\_\_

**10. CHARACTER OF LINES, NUMBERS, & LETTERS.** 37 CFR 1.84(k)

Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (poor line quality). Fig(s) \_\_\_\_\_

**11. SHADING.** 37 CFR 1.84(m)

Solid black areas pale. Fig(s) \_\_\_\_\_

Solid black shading not permitted. Fig(s) \_\_\_\_\_

**12. NUMBERS, LETTERS, & REFERENCE CHARACTERS.** 37 CFR 1.84(p)

Numbers and reference characters not plain and legible. Fig(s) \_\_\_\_\_

Figure legends are poor. Fig(s) \_\_\_\_\_

Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1) Fig(s) \_\_\_\_\_

English alphabet not used. 37 CFR 1.84(p)(2) Fig(s) \_\_\_\_\_

Numbers, letters and reference characters must be at least 32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3). Fig(s) \_\_\_\_\_

**13. LEAD LINES.** 37 CFR 1.84(q)

Lead lines missing. Fig(s) \_\_\_\_\_

**14. NUMBERING OF SHEETS OF DRAWINGS.**

37 CFR 1.84(q)

Sheets not numbered consecutively, and in Arabic numbers beginning with number 1. Sheet(s) \_\_\_\_\_

**15. NUMBERING OF VIEWS.** 37 CFR 1.84(u)

Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) \_\_\_\_\_

**16. DESIGN DRAWINGS.** 37 CFR 1.152

Surface shading shown not appropriate.

Fig(s) \_\_\_\_\_

Solid black surface shading is not permitted except when used to represent the color black as well as color contrast. Fig(s) \_\_\_\_\_

COMMENTS:

Reviewer [Signature]  
If you have questions, call (703) 305-8404.

Date 10/30/03  
Attachment to Paper No. 24

PTO/SB/08A (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
Information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO  <h1>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h1>  (use as many sheets as necessary)				Complete if Known <table border="1"> <tr> <td>Application Number</td> <td>09/782,594</td> </tr> <tr> <td>Filing Date</td> <td>2/12/2001</td> </tr> <tr> <td>First Named Inventor</td> <td>Bianchi et al.</td> </tr> <tr> <td>Group Art Unit</td> <td>1615</td> </tr> <tr> <td>Examiner Name</td> <td>Unknown</td> </tr> <tr> <td>Attorney Docket Number</td> <td>RTI-112R</td> </tr> </table>		Application Number	09/782,594	Filing Date	2/12/2001	First Named Inventor	Bianchi et al.	Group Art Unit	1615	Examiner Name	Unknown	Attorney Docket Number	RTI-112R
Application Number	09/782,594																
Filing Date	2/12/2001																
First Named Inventor	Bianchi et al.																
Group Art Unit	1615																
Examiner Name	Unknown																
Attorney Docket Number	RTI-112R																
Sheet	-1	of	2														

[illegible][illegible]

Examiner Signature	<i>Paul R. Lister</i>	Date Considered	10-30-03
-----------------------	-----------------------	--------------------	----------

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**

PTO/SB/08B (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
Information unless it discloses a valid OMB control number.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231.

## **EXHIBIT 9**



ATTORNEY DOCKET NO. RT1 112R/1915-13980US02

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:

Bianchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

Group Art Unit: 3738

Examiner: Paul B. Prebilic

CERTIFICATE OF MAILING

I hereby certify that this document and all documents referred to herein are being sent by first class mail, postage prepaid, to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

May 04, 2004

Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.111

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of 11/04/03, for which a response is due 02/04/04, now extended three months to 05/04/04, the Applicants respond as follows:

Amendments to the Abstract:	Page 2
Amendments to the Claims:	Pages 3-5
Remarks:	Page 6

**Amendment to the Abstract:**

Please delete the paragraph in the Abstract and substitute therefor the following paragraph:

~~This invention provides a method for manufacture of autograft, allograft and xenograft implants which comprises assembling such implants from smaller pieces of graft materials to form a larger graft implant product~~ is directed to an assembled implant comprising two or more portions of bone that are held together in appropriate juxtaposition with one or more biocompatible pins to form a graft unit. Preferably, the pins are cortical bone pins. Typically, the cortical bone pins are press-fitted into appropriately sized holes in the bone portions to achieve an interference fit. The bone portions are allograft or xenograft.

**Amendments to the Claims:**

Please substitute the listing of the claims as provided below for any prior listings:

Claims 1-25 (Cancelled)

26. (Currently Amended) An assembled A-composite bone graft, comprising: a plurality of bone portions layered to form a graft unit, and one or more biocompatible ~~connectors~~ pins traversing said graft unit for ~~holding together said graft unit together,~~ said ~~biocompatible connectors do~~ assembled bone graft does not comprise an adhesive.

27. (Currently Amended) An assembled A-composite bone graft comprising:  
two ~~or more~~ distinct bone portions of cortical bone, and one or more biocompatible ~~connectors~~ pins, wherein said biocompatible ~~connectors~~ pins are press fitted into machined holes in said two bone portions to hold together said two ~~or more~~ bone portions to form said composite bone graft; ~~said biocompatible connectors do not comprise~~ an adhesive.

28. (Currently Amended) An assembled A-composite bone graft comprising two or more connected, distinct, bone portions forming a graft unit, and two or more cortical bone pins, said two or more connected, distinct, bone portions having holes therein for receiving said two or more cortical bone pins, said cortical bone pins keeping said two or more connected, distinct, bone portions aligned and connected, without distinct, bone portions do not comprise an adhesive.

29. (Currently Amended) The assembled A-composite bone graft of claim 28 comprising three ~~or more~~ connected, distinct, bone portions; ~~said connected, distinct, bone portions are not connected with an adhesive.~~

30. (Currently Amended) The assembled composite bone graft of ~~any one of~~ claim ~~26~~ 28, wherein said two or more connected, distinct, bone portions are selected from the group consisting of: cortical bone and cancellous bone.

31. (Currently Amended) An assembled A-composite bone graft, comprising:

a first bone portion having one or more holes therein;

a second bone portion having one or more holes therein aligned with the holes in said first bone portion;

~~a third bone portion, said first, second and third bone portions are layered to form a graft unit; and~~

one or more ~~biocompatible connectors~~ cortical bone pins press-fitted in said holes for holding said first bone portion in juxtaposition to said second bone portion and forming a together-said graft unit; ~~said biocompatible connectors do not comprise an adhesive.~~

32. (Currently Amended) An assembled A-composite bone graft, comprising:

a first cortical bone portion having a hole therein;

a second cortical bone portion having a hole therein, said hole aligning with said hole in said first cortical bone portion;

a cancellous bone portion press fitted in the hole disposed between said first cortical bone portion and said second cortical bone portion to form said assembled bone a graft unit; and

~~one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.~~

33. (Currently Amended) An assembled A-composite bone graft, comprising:

a first cortical bone portion having one or more holes therein;

a second cortical bone portion having one or more holes therein aligned with the holes in said first bone portion provided on said first cortical bone to form a graft unit; and

one or more ~~biocompatible connectors~~ cortical bone pins press-fitted in said holes for holding said first cortical bone portion in juxtaposition to said second cortical bone portion and forming a; ~~connecting said graft unit, said biocompatible connectors do not comprise without an adhesive.~~

34. (Currently Amended) An assembled A-composite bone graft, comprising:

a first bone portion;

a second bone portion provided on said ~~first~~ bone portion to form a graft unit; and

one or more biocompatible ~~connectors~~ pins inserted into said first bone portion and said second bone portion for holding together said graft-unit, ~~said biocompatible connectors do not comprise an adhesive.~~

35-60. (Cancelled)

## REMARKS

The amendments to the claims do not add new matter. The amended claims merely recite elements in the originally filed claims. In the claims, the word "assembled," which replaces the word "composite" is used throughout the specification. More importantly, the amended claims are fully supported by the disclosure in Applicants' priority application USSN 08/920,630, a copy of which is attached hereto as Exhibit A. In particular, the Examiner's attention is drawn to Figures 7 and 8 therein and the discussion thereof, beginning at page 16, line 29 through page 18, line 6.

The Examiner requested an Abstract that more accurately reflected the invention being claimed. The Abstract has been amended in conformity with the presently pending claims.

### Summary of the Bases for Objection/Rejection

The Patent Office noted that there was no original claim 48 in the specification and requests that claims 49-61 be renumbered as claims 48-60.

The Patent Office requests affirmation of the election of invention of Group Va (claims 26-42, 44 and 46-60).

The drawings are objected to because of crossing hatching (FIGs. 6-7, 13-14, 18, 20C, 21D, 21E and 22D) and labeling (FIG. 1) issues.

The Patent Office commented on the IDS filed 10/09/01.

Claims 38, 41-42 and 53-55 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite.

Claims 26-42, 44 and 46-60 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.).

Claims 26-31, 33-35, 37-38, 40, 42, 49-50, 53-55 and 60 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,025,538 (Yaccarino).

Each of these bases for objection and/or rejection is addressed in Sections I-VII which follows.

## **I. Renumbering of the Claims**

The Patent Office noted that there was no original claim 48 in the specification and requests that claims 49-61 be renumbered as claims 48-60. In response, the Applicants have amended the claims 49-61 to be renumbered as claims 48-60. In addition, the Applicants amended the claim dependencies in renumbered claims 49 to 60 to reflect the renumbering that occurred. Accordingly, this basis for objection has been rendered moot.

## **II. Affirmation of Election of Species**

The Patent Office requests that the Applicants affirm their election to prosecute the invention of Group Va (claims 26-42, 44 and 46-60). In response, the Applicants hereby affirm their election to prosecute the invention of Group Va (claims 26-42, 44 and 46-60).

## **III. Objection to some of the Drawings**

The Patent Office has objected to certain drawings because of cross hatching (FIGs. 6-7, 13-14, 18, 20C, 21D, 21E and 22D) and labeling (FIG. 1) issues. Specifically, the Patent Office objects to FIGs 6-7, 13-14, 18, 20C, 21D, 21E and 22D because the cross-hatching therein indicates "metal" rather than "bone components." In addition, the Patent Office objects to FIG. 1 because it is not labeled as FIG. 1. In response, the Applicants resubmit substitute FIG. 1 (sheet 1/14), now labeled as FIG. 1.

Regarding FIGs. 6-7, 13-14, 18, 20C, 21D, 21E and 22D, the cross hatching is shown as running from top left toward bottom right--like a slash mark. In contrast, the MPEP shows that the cross hatching for a metal runs opposite that of the Applicants, running from top right to bottom left--like a back-slash. Further, the MPEP also shows that for biochemical components, the correct direction of the hatching is as used by the Applicants running from top left to bottom right. In addition, the hatching for biochemical inventions also includes a series of horizontal dashes and crescent moons. The latter were not included in the applicants' drawings as they would obscure the details of the drawings. FIG. 20C, which had cross-hatching going in both directions was corrected by deleting the cross hatching going from top right to bottom left. A copy of corrected FIG. 20C (sheet 8/14) is

cofiled herewith. No new matter has been added. In light of these amendments and this explanation, it is believed that all bases for rejection of the drawings have been rendered moot.

#### **IV. Lost Reference**

The Patent Office indicates that the Gie, *et al.* reference contained in the IDS filed 10/05/01 was lost in the Patent Office. Since the filing of that IDS, the application has been transferred to the present counsel. However, the transferred file did not contain that reference. Accordingly, the Applicants have ordered that reference to make it of record. The reference will be filed as soon as it is received.

#### **V. 35 U.S.C. § 112, Second Paragraph**

Claims 38, 41-42 and 53-55 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. According to the Patent Office, the Markush group of claim 38 is unclear because of the multiple use of “and” and “or.” In response, the Applicants have cancelled claim 38, thereby rendering this basis for rejection moot.

The Patent Office has rejected claims 41-42 based upon the recitation of the term “plate-like,” which is alleged to be unclear. Similarly, the Patent Office has rejected claims 53-55 based upon the recitation of the term “peg-like,” which is alleged to be unclear. In response, the Applicants have cancelled claims 41-42 and 53-55, thereby rendering this basis for rejection moot.

#### **VI. 35 U.S.C. § 102(e) over U.S. Pat. 6,200,347 (Anderson)**

Claims 26-42, 44 and 46-60 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.). Applicants have amended claims 26-34 in conformity with the Applicants priority application USSN 08/920,630, filed 08/27/97. Accordingly, Anderson, which has an earliest claimed priority date of 01/05/99 is no longer prior art.

**VII. 35 U.S.C. § 102(e) over U.S. Pat. 6,025,538 (Yaccarino)**

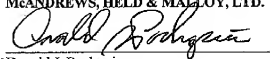
Claims 26-31, 33-35, 37-38, 40, 42, 49-50, 53-55 and 60 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,025,538 (Yaccarino). Applicants have amended claims 26-34 in conformity with the Applicants priority application USSN 08/920,630, filed 08/27/97. Accordingly, Yaccarino, which has an earliest claimed priority date of 11/20/98 is no longer prior art.

For these reasons, the allowance of claims 26-34 is respectfully requested.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:



Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8133

Date: May 04, 2004

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DESCRIPTION

CORTICAL BONE CERVICAL SMITH-ROBINSON FUSION IMPLANT

1.0 Background of the Invention

1.1 Field of the Invention:

This invention relates to a cortical bone implant for use in cervical Smith-Robinson vertebral fusion procedures, as well as methods for the manufacture and use thereof.

1.2 Background Art:

Since at least the mid to late 1950's anterior cervical spinal fusions have been performed in order to alleviate chronic neck, arm and shoulder pain caused by trauma, disc herniation, or spondylosis (Robinson and Smith, 1955; Smith and Robinson, 1958). The classic procedure referred to as the Smith-Robinson cervical fusion employs a horseshoe-shaped graft to promote vertebral fusion (Robinson *et al.*, 1962). The Cloward technique employs a cancellous bone dowel (Cloward, 1958), and the Bailey-Badgley procedure uses a strut (Bailey and Badgley, 1960). In a study comparing the compressive load capacity of the various implants used according to these procedures, it was found that the Smith-Robinson graft could sustain loads up to 344 N, the Cloward dowel could sustain loads of up to 188 N, and the Bailey-Badgley type could sustain loads up to 195 N, (White and Hirsch, 1972). In a modified Smith-Robinson procedure, the horseshoe-shaped implant is inserted with the cortical end of the implant located posteriorly, which has been reported to increase the fusion rate while decreasing the graft extrusion and collapse sometimes experienced with the Cloward dowels (Whitecloud and Dunsker, 1993). However, in a recent study evaluating the success and relief rates achieved according to these procedures, it was found that less than 100% success rate (fusion, patient improvement and absence of complications) was achieved, regardless of which method or implant was used (Grooms *et al.*, 1996).

U.S. Patent No. 5,306,309, discloses a spinal disk implant comprising a solid body of

biocompatible synthetic material arranged to define a right-rectangular solid having two opposed side faces and two opposed transverse faces, including a convexly curved anterior face and a posterior face, for implantation in the intervertebral space. The discussion of vertebral and intervertebral morphology is hereby incorporated by reference.

5 U.S. Patent No. 5,609,635, discloses a lordotic interbody spinal fusion implant comprising a wedge shaped metallic cage for insertion into the intervertebral space.

U.S. Patent No. 5,306,307, discloses a ceramic spinal disk implant having a serrated edge.

None of these references disclose a cortical bone intervertebral implant having a substantially "D"- or bread-loaf-shaped structure having a canal into which osteogenic materials  
10 may be packed, which sustains spinal loads, and which is remodeled into the spine in the course of fusion. Accordingly, the present invention addresses the need in the art for improvements to both the implant and the avoidance of post-surgical complications from anterior cervical fusions. The present invention provides a new cortical bone implant for use in achieving anterior cervical fusions when implanted according to the Smith-Robinson procedure. In addition, in view of the  
15 peculiar characteristics of bone, the present invention comprises unique methods and apparatuses for the manufacture of the substantially "D"-shaped cortical bone implant.

## 2.0 Summary of the Invention

20 An implant composed substantially of cortical bone is provided for use in cervical Smith-Robinson vertebral fusion procedures. According to methods of this invention, the implant is derived from allograft or autograft cortical bone sources, is machined to form a substantially "D"-shaped implant having a canal into which osteogenic material may be packed. The implant is inserted into the space between adjacent cervical vertebrae to provide support and induce fusion  
25 of the adjacent vertebrae.

### 3.0 Brief Description of the Drawings

Figure 1 provides several views of the fusion implant of this invention.

Figure 2 provides views of the core cutter and drill assembly and the bone plug formed by cutting  
5 into the diaphysis of a long bone when such a core cutter and drill assembly is used.

Figure 3 provides a view of broach as used according to this invention and an asymmetric canal  
formed by use of such a broach.

Figure 4 provides several views of an apparatus for machining a profile on the exterior surface of  
the implant of this invention.

10 Figure 5 provides a view of an apparatus for inscribing retention teeth in the upper surface, lower  
surface or both upper and lower surfaces of the implant.

Figure 6 provides several views and dimensions for specific embodiments of the implant of this  
invention.

Figure 7 provides a view of a stacked embodiment of the implant of this invention.

15 Figure 8 provides several views of an implant of this invention formed by juxtaposition of mirror  
image halves of the implant.

### 4.0 Detailed Description of the Invention

20 According to this invention, a substantially "D"-shaped cortical bone implant for cervical  
Smith-Robinson fusions is produced, preferably under aseptic conditions. Class 10 clean room  
processing is desirable, and sterilization of all machining tools is likewise preferred, (particularly  
after switching from one allograft donor to the next), so that the finished product may be treated  
by standard techniques known in the art (alcohol, peroxide, or like treatments), prior to storage  
25 and shipment to physicians for use in implantation procedures. Because of the peculiarities of  
working with bone, and in particular, because of the desirability of maintaining aseptic  
conditions while working with this material, novel approaches have been adopted in the  
production of the product of this invention.

The implant is preferably formed from cortical bone obtained from tibia, femur or other

source of strong cortical bone. The bone source may be autograft or, due to possible complications at the donor site (infection, pain, delayed healing), is preferably, allograft bone. In addition, it is critical that the source bone be derived from a donor whose medical history is well known (absence of transmissible diseases, cancer, osteoporosis), and that the donor bone be obtained under aseptic conditions according to accepted practices in the art of tissue banking. In addition, extensive *in vitro* testing should be conducted to ensure the absence of pathogenic agents.

The approach adopted in describing the implant of this invention is to first provide a narrative disclosure of preferred methods for making the implant, followed by a detailed description of the implant itself, followed by a detailed description of various apparatuses and aspects of the machining process, and finally, a detailed description of the method of using the implant.

#### 4.1 Narrative Description of Implant Manufacture

While any shape of cortical bone may be used to begin with, we have found that for consistent production of cortical bone which may be reliably machined, it is advantageous to commence with a plug of bone which extends from the exterior of the diaphysis of a long bone toward the intramedullary canal (where, *in vivo*, the bone marrow resides). The result is a bone plug or dowel which has an outer substantially cortical end and an internal end which is composed largely of soft cancellous bone. In cutting the bone plug, we have discovered that the use of a core cutter is convenient. This device comprises an outer coring element of any desired diameter, whereby the diameter of the bone plug is defined, and a centrally located solid drill bit, which provides a canal through the center of the bone plug as well as stability for the core cutting element. The core cutter-drill assembly is preferably torqued by an air drill, driven by sterile air, and the source bone is preferably immobilized in a sterilized vice during the core-cutting process.

We have discovered that in the above-described manner, cortical bone implants may be fashioned having heights, widths and lengths which are practically useful in the Smith-Robinson cervical fusion method. According to this method, the height of the implant is only limited by

the distance from the exterior of the bone diaphysis to the intramedullary canal. However, we have discovered that, by this method, final implant heights from about 7 mm to about 14 mm may be produced, depending on the choice of bone source and the location on the bone from which the bone plug is cored. Since it is extremely rare for the cervical intervertebral space to extend beyond these limits, this method is therefore capable of supplying implants of required or useful heights. Likewise, the length and width of the implant are defined by the diameter of the core-cutter, and final lengths and widths of between about 7 and 14 mm are easily provided for by this method. In addition, where the need arises for heights between about 10 mm and 14 mm, or if difficulty is experienced in obtaining donor bone having a sufficient width from the exterior of the bone to the intra-medullary canal to provide such heights, alternate methods of producing the implant of desired heights disclosed herein may be employed. For example, in a first such alternate method, implants of this invention are produced and then stacked to provide a unitary implant of the desired height dimensions. Such stacked implants may be maintained in a unitary association by drilling appropriate holes through the height of the implant, and inserting therein appropriate retention pins made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium or other metallic retention pins. In a further alternate method, a section of cortical bone along the long axis of a long bone may be machined according to methods known in the art. By then further shaping and cutting appropriate heights in such cortical bone, and bringing halves of the implant into juxtaposition with each other, implants of any desired shape and height are produced.

Continuing with a description of the first method for making the implant of this invention, the cancellous bone on the internal side of the bone plug is removed by any convenient means, including with a saw, an abrasive means such as a diamond tipped rotary sander, or a tooling bit mounted in a lathe, to produce a "washer" shaped piece of substantially cortical bone. Both the internal and external ends of the bone plug should be machined flat, thereby forming a top face and a bottom face, each of which is substantially planar, and preferably parallel. While the cancellous bone is partially or completely removed by this process, there remains a slight difference in the density of the bone from the external (cortical) to the internal (cancellous or originally intra-medullary) aspect of the bone plug. It is desirable to record the orientation of the

bone plug as subsequent machining steps proceed most efficiently when machined from the external aspect toward the internal aspect.

In order to accommodate subsequent machining steps and to provide an orientation to the implant according to which the surgeon may properly insert the implant, the circular internal canal formed by the centrally located solid drill bit of the core-cutter is modified to form an asymmetric shape, such as a key way. This may be achieved by any of a number of different means, including drilling a slot into an aspect of the internal canal closest to the external (more dense cortical) end of the dowel. However, in a preferred embodiment of this invention, we have found that an implant of consistently good final quality may be machined by conversion of the circular canal into a substantially "D" shaped canal having three essentially rectangular walls and a fourth convexly curved wall. We have found that it is desirable for the curvature of the convexly curved wall to approximate the external curvature of the bone plug. This modification may be achieved by any of a variety of means. However, we have invented an efficient means by which consistently usable implants may be reproducibly machined. This is accomplished by immobilizing the implant, for example in an arbor press assembly, and, preferably from the originally cortical external (denser) end of the implant, slowly forcing a broach through the originally circular canal. The broach is preferably a hard metallic member having a plurality of spaced-apart ribs or rings machined therein, with indentations provided between each ring which thereby form the spacing between adjacent rings. In addition, the edges of each ring are desirably very precise, angular, and sharp, such that as the broach is forced through the originally circular internal canal, the sharp cutting edge of each ring shaves off an incremental amount of bone as the ring passes through the implant. Each ring of the plurality of rings has a shape which, starting at the insertion end of the broach is tapered from an essentially circular shape to any desired final shape for the canal. Accordingly, in one embodiment of this invention, the transition from a circular shape to a substantially "D"-shaped profile over several inches and over a plurality of spaced apart rings. It will be appreciated that the length of the broach and the number of rings used is defined by the amount of bone that must be removed to form the new shape, the width of each ring and the width of the space between each ring. Removal of no more than about 0.004" of bone by each ring has been found to be a sufficiently small transition to

ensure that the vast majority of implant blanks survive this machining step. Broaches of approximately 6" in length have been found adequate for most implant shapes, but for very asymmetric shapes (e.g. an implant which is 11 mm wide and 14 mm long), more bone would need to be removed to form the "D"-shaped canal than from a symmetric implant (e.g. a 14 mm wide by 14 mm long implant). This need may be accommodated by use of more than one broach, with the shape of the insertion end of each consecutive broach substantially matching the shape of the last ring on the previous broach.

Having formed an asymmetric shape, such as a key way, from the internal canal running through the implant, we have found it desirable to modify the external profile of the implant from a substantially circular shape to another desired form. In a preferred embodiment of this invention, the external form of the implant is machined so as to proportionately match the shape of the substantially "D"-shaped internal canal. An external "D"-shaped profile has been used in implants known in the art (see for example U.S. patent 5,306,309; 5,522,899) made from materials other than bone, because of the ability of the convexly curved face of the implant to substantially match the curvature of the anterior aspect of the intervertebral disk into which the implant is to be inserted, as well as to provide efficient spinal load distribution over the remainder of the implant. However, due to the peculiar nature of bone, and the requirements of aseptic or sterile manufacturing, inventive methods and apparatuses were required to produce the desired external profile for the cortical bone implant. It will be recognized that, based on the instant disclosure, a substantially "D"-shaped external profile of the implant may be machined by a variety of means which vary from the precise methods disclosed herein. In addition, other external profiles than the "D"-shaped profile are likewise enabled by modifications of the methods and apparatuses disclosed herein for formation of the "D"-shaped external or internal profile.

We have found it convenient and reproducible to use either of two principal methods for machining the external profile. The implant, with the "D" or alternately shaped internal canal being used as a key way, is fitted onto the end of a spindle which precisely matches the shape of the internal canal of the implant, thereby providing purchase for machining of the external profile of the implant. In a first preferred method, as the implant is rotated on the spindle, it is contacted

with an asymmetric generator (grinding) wheel attached to a cog which meshes at a known registration point with a cog to which the spindle with the implant is attached. The speed of rotation of the exterior of the spindle mounted implant, and the exterior of the generator wheels are designed to differ such that as the generator wheel and implant are contacted and are rotated in fixed registration, the generator surface (which is preferably an abrasive diamond plated surface), grinds bone from the external surface of the implant, to form a profile thereon defined by the asymmetric shape of the grinder wheel.

In a second external profile generation method, the implant, with the "D" or alternately shaped internal canal being used as a key way, is fitted onto the end of a spindle which precisely matches the shape of the internal canal of the implant, thereby providing purchase for machining of the external profile of the implant. In this method, the spindle is affixed to an asymmetric cam which rotates concentrically with the spindle, and therefore the implant. The thus mounted implant is contacted with a cutter means, such as a sharp bit having cutting edges which rotate about an adjacent axis. The implant mounted spindle riding on the asymmetric cam is biased to contact the rotating cutter, which thus traces a profile onto the exterior of the implant defined by the shape of the asymmetric cam. For purposes of this disclosure, use of the term "asymmetric cam" should be understood to mean any desirable shape such that upon production of the implant, the shape thereof is defined by that of the asymmetric cam. Shapes contemplated by this disclosure include, but are not limited to, elliptical shapes, D-shapes, partially curved shapes, and the like.

Once the external profile has been machined, the implant is removed from the spindle, and the machining of the implant may either be terminated, to provide a substantially "D"-shaped cortical bone implant with flat upper and lower surfaces, or an external feature may be machined into the upper and lower surfaces to prevent backing out of the implant upon insertion into the intervertebral space. This may be achieved by a number of means, such as by machining annular rings, indentations and projections, ribbing or teeth into the upper, lower, or both surfaces of the implant. In a preferred embodiment of this invention, the implant is passed through a set of opposing jaws bearing teeth which broach a tooth-shaped profile into the implant as it is forced through the jaws. Alternatively, the implant is passed several times over a ridged surface which

cuts the desired tooth profile into the upper, lower or both surfaces of the implant. Preferably, the thus formed teeth angle toward the anterior (convexly curved) face of the implant to prevent backing out of the implant once it is inserted into an appropriately shaped cavity formed in the intervertebral space in an anterior aspect of the cervical spine. In order to accommodate the difficulty surgeons experience in forming precise angles when forming such cavities in the spine, (see for example U.S. patent No. 5,397,364 disclosing a beveled edge to reduce trauma upon insertion of a metallic spinal implant), a beveled edge of defined radius is preferably machined into three faces of the implant, but leaving the anterior face unbeveled. The sharp anterior edge, like the teeth in the upper and lower surfaces of the implant, retards backing out of the implant.

#### 4.2 Detailed Description of the Implant

Referring now to figure 1A, there is shown a top view, as if viewed from the top of the spinal column, of a substantially "D"-shaped cortical bone implant 100. The implant has a wall thickness 101, a length 103, a width 102, and an internal canal 104, which fall within desired tolerances (see discussion below). The implant comprises four contiguous walls, including a substantially straight rear wall 105, substantially straight side walls 106 and 107, and a preferably curved front wall 108. In figure 1B, there is shown a side view of the implant 100, revealing the height 109, of the implant. In addition, this view shows, in outline, the internal side walls 106' and 107' of the internal canal, 104. It also shows the top 110 and bottom 111 surfaces of the implant. In figure 1C, there is shown a top view of an embodiment of the implant 100 in which an external feature 120 has been inscribed onto the top 110 and bottom 111 surfaces of the implant. In addition, a "radius" or bevel 115 is shown on the two side and posterior edges of the implant. Figure 1D shows a side view of the implant 100 in which the inscribed feature 120 can clearly be seen in the top 110 and bottom 111 surfaces of the implant. In this view, it can be seen that the external feature 120 has the side profile of a set of teeth, all of which angle toward the anterior face 108 of the implant. An outline of the bevel 115 is also evident in this view, as is the rounded posterior edge 105. As can be seen, in this embodiment of the invention, the anterior edge 108 is maintained with a sharp edged. In figure 1E, there is shown a detail of one

embodiment of the inscribed feature 120 on the portion of the implant indicated in figure 1D. In a preferred embodiment, the feature 120 defines a tooth-like structure, with teeth 121 separated from each other by concavities 122. An angle  $\theta$  defines the grade of the concavity as it ramps to the tooth. The tooth height 123, space between teeth 124, and aperture of the concavity 125 may all be defined by the manufacturer to optimize retention of the implant within the cervical spine after proper placement.

#### 4.3 Detailed Description of the Method of Manufacturing the Implant

Because of the peculiar nature of bone, and the desirability of sterile or aseptic manufacturing, specific and specialized procedures and apparatuses are required for successful formation of the implants of this invention. Those skilled in the art will recognize that, based on the methods and apparatuses disclosed herein, the implant of this invention may be manufactured by alternate means suggested by those described herein. Nonetheless, through careful design and knowledge of bone structure, instruments for the manufacture of the implant of this invention have been invented for this purpose. In what follows, specific details with respect to preferred method and apparatuses for making the implant of this invention are provided. It should be recognized that the invention should not be construed as being limited to these specifics.

Referring to figure 2, there is shown in side view in figure 2A a core cutter 200, having a core bit 201 which is affixed by a set screw 203 to the shaft 204 of a drill bit 202, centrally located within and coaxial with the core cutter. In figure 2B, an end-on view of the core cutter 200 is provided showing the set screw 203 in outline. Figure 2C shows a side view of the bone plug 210 which is formed by cutting a plug of bone from the diaphysis of a long bone using the core cutter 200. At one end, 211, originally the external cortical surface of the bone shaft, there is a substantially cortical bone surface through which a hole 213 is formed by the central bit 202 of the core cutter 200. The other end, 212, is an irregular and bone surface which, *in vivo*, formed part of the wall of the intramedullary canal. Cancellous bone or other microstructure at the end 212 is removed, and both ends are ground, cut or otherwise machined to be substantially flat and parallel, to form the substantially cortical bone plug 210 shown in figure 2D.

Referring to figure 3, there is shown in figure 3A an internal canal profile broaching tool 300. A plurality of spaced-apart ribs or rings 301 are provided along the length of the broach which taper from a substantially circular shape at the insertion end 302 of the broach, to substantially "D"-shaped rings 303 (or any other desired shape) at the completion end 304 of the broach 300 (intermediate ribs 305 are not shown; rather, the outline of the taper angle is shown). A notch or groove 306 is provided in the broach completion end 304 for releasably affixing the broach into a means, such as a press, for forcing the broach through the implant canal. In figure 3B, there is provided an end-on view of the cancellous bone plug 310 after the broaching procedure is completed. As can be seen, the internal canal 104 has been converted from a circular canal into a substantially "D"-shaped canal. As will be appreciated from this disclosure, any of a number of different asymmetric shapes in the internal canal 104 may be defined by this or analogous means, the principal goal being to provide a purchase (referred to herein as a "key way") within the implant for external machining of the implant.

Having formed a key way within the implant, it is possible to modify the external profile of the implant. In one aspect of this invention, referring to figure 4A, this is conveniently achieved by affixing the implant 410 to the spindle 420 of a lathe 400. The spindle shaft 440 extends, through bearings (not shown), to a means 450 (such as a handle or a motor) for rotating the spindle. Affixed to the spindle-shaft is a cam 430, the shape of which defines the ultimate external profile of the implant 410. The spindle shaft 440 and bearings are mounted in a cross slide 441, which translates in a first plane, referred to as the "Y-plane". Motion in the Y-plane is limited by contact of the cam 430 with a limiting means 460 such as a cam follower, which remains in register with a carriage 442 which translates along a plane, the "X-plane", transverse to the Y-plane motion of the cross-slide. The cross-slide is mounted in a slide-way 443 of the carriage 442, which in turn is slideably mounted on the bed 444 of the lathe, such that the carriage 442 is permitted to translate along the X-plane. Travel of the slide 442 along the X-plane is limited by means of a stop screw 470.

Further detail of this means for generating the external profile of the implant is provided in figure 4B, which provides a side view of one specific embodiment of the implant external profile generator 400. An air driven turbine within housing 401 provides a source of torque to

turn a shaft 402. A means for cutting or grinding the external surface of the implant 410, such as an appropriately fashioned cutter or bit having a non-cutting end 403 for fixation to the shaft 402. Extending from the non-cutting end 403 which has a first diameter, is a cutting surface 404, having a second, smaller diameter. A "shoulder" 405, forms a radius extending between the smaller diameter of the cutting surface 404 and the larger diameter of non-cutting surface 403. The cutting surface 404 is contacted with the implant blank 410, mounted on spindle 420, to which, as described above is mounted an asymmetric cam 430. The thus mounted implant blank 410 is brought into contact with the cutting surface 404, by virtue of translation in the X-plane of the carriage 442. The spindle 420, and thus the asymmetric cam 430 are rotated, manually or by motor driven means, through shaft 440 and handle 450 which are attached concentrically with the cam 430. Preferably, the asymmetric cam 430 is elastically biased toward a stationary cam follower 460. In this fashion, after several revolutions of the handle 450, the shape of the asymmetric cam 430 generates the desired external profile of the implant 410 riding on the spindle 420, through contact with the rotating cutting surface 404.

To ensure that the implant blank is machined only up to the point that the forward edge 411 of the implant approaches but does not contact the "shoulder" 405 on the cutter, a stop screw 470 is provided. The stop screw 470 is set to prevent further advancement of the implant blank 410 by stopping advancement of the carriage 442 when the leading edge 471 of the stop screw comes into contact with a measuring screw 480. The appropriate setting of the stop screw 470 is achieved at the start of the milling process by first placing the implant 410 between the end 481 of the measuring screw 480 and an anvil 482, and tightening the measuring screw 480 until it just makes contact with the implant. In this fashion, the measuring screw 480 and anvil 482 essentially form a micrometer, with the gap being defined by the width of the implant. Both the measuring screw 480 and anvil 482 are housed within a measuring slide 483 which, when slid all the way to the left as shown in figure 4B, abuts a rotateable stop cam 490, retained within the same slide-way as the measuring slide 483 by a retainer 484. The rotateable stop cam 490 may be set in either of two positions, which produces a difference in the stopping point of the stop screw 470 of approximately 0.06". The significance of this difference is that the first position arrests advancement of the stop screw 470 (and therefore the carriage 442) just before the

implant 410 contacts the radius shoulder 405 of the cutting surface 404. In the second position, the stop cam 490 allows the stop screw to advance the additional approximately 0.06" to allow contact of the implant 410 with the shoulder 405 of the cutting surface 404 to thereby bevel the edges of the implant 410 that are thus contacted. Accordingly, in the pre-milling setup, the stop  
5 cam 490 should be rotated such that the stop screw 470 is forced to stop the extra 0.06", following which a further processing step may be carried out in which the stop cam 490 is rotated to the second position in which the stop screw 470 is allowed to advance this additional approximately 0.06".

In figure 4C, there is provided an end-on, rear view (i.e. looking from the handle 450  
10 toward the spindle 420) of the asymmetric cam 430, the spindle 420 and the implant 410. In addition, in this detail view, an additional feature in the asymmetric cam 430 is seen as a diminution in the thickness along three faces 431 of the asymmetric cam 430 which is a relief in the rear of the asymmetric cam 430. The significance of this relief 431 is that it restricts the contact of the implant 410 with the shoulder 405 to the extent defined by the relief in the rear of  
15 the asymmetric cam 430. As noted above, in fashioning an implant site in the intervertebral space during a partial discectomy, surgeons are unable to produce perfectly sharp angles. To accommodate this imperfection, to prevent trauma upon insertion of an implant with sharp edges, and to create as tight-fitting an implant as possible, the fashioning of a bevel around the edges of the implant that are inserted into the intervertebral space created by the surgeon is desired. At the  
20 same time, in order to prevent backing out of the implant, it may be desirable to retain a sharp anterior implant edge, and therefore the relief in the cam 430 does not extend completely around the cam. Thus, upon completion of the external profile of the implant 410 as described above, the carriage 442 is backed away from the cutter, the stop cam 490 is flipped to its second position allowing advancement of the stop screw 470 the additional approximately 0.06" mentioned  
25 above. At the same time, a shot pin 432 is advanced into the relief 431 by means of a shot pin mover 433, thereby allowing rotation of the cam 430 only to the extent permitted by the shot pin 432 as it rides within the relief 431. With the shot pin 432 riding in the relief 431, the "shoulder" 405 contacts the leading edge 411 of the implant blank 410, thereby rounding three edges of the implant 410. After machining the leading edge 411 of the implant 410, the implant is removed

from the spindle 420, turned around, and re-positioned on the spindle 420, to inscribe the bevel on three edges of the other side of the implant.

In figure 4D, a frontal view is provided of the spindle 420, the implant 410, the asymmetric cam 430, and the cam follower 460. Also shown is the cam adapter 461, by means of which the cam follower 460 is affixed to the carriage 442, and by means of which the cam follower 460 maintains the cutting surfaces 404/405 in contact with the implant 410 as defined by the shape of the asymmetric cam 430. Also shown is a part of the cross-slide 441, which is preferably biased or which may be pushed manually toward the cam follower 460.

In figure 4E, a side detail view is provided of the stop cam 490. In this view, a stop cam handle 491 is shown which allows the operator of the implant outside profile generator to fix the stop cam 490 in a first position A, and a second position B, whereby additional travel of the stop screw 470, and thereby advancement of the carriage 442, is provided in position B, of about 0.06" due to the difference in the distances shown for these positions.

By means of the apparatuses and method described above, a cortical bone implant 100 as shown in figure 1 having a substantially "D"-shaped external profile, and a substantially "D"-shaped internal canal is produced. Naturally, based on this disclosure, those skilled in the art will appreciate that other shapes, both for the external profile and internal canal of the implant may be produced. For example, an ellipsoid is produced by the above described methods simply by modification of the shape of the asymmetrically shaped cam 430; and the internal canal shape may be modified by drilling, routing, or broaching using a broach that tapers to any desired shape. The thus formed implant may be used after machining as described, followed by appropriate cleaning methods known in the art (e.g. bathing in alcohol, peroxide treatment etc.). In addition, however, it may be desirable to inscribe an external feature on the upper surface 110, the lower surface 111, or both. Such a feature may take any desirable form, such as annular rings, indentations, projections, ribbing or teeth. In a preferred embodiment, teeth sloping toward the anterior aspect 108 of the implant are inscribed onto the top 110 and bottom 111 surfaces of the implant by forcing the implant through opposed broaches bearing inscribing teeth. Alternatively, the upper 110, lower 111 or both surfaces in turn may be repeatedly run, manually or by a machine-driven means, over an appropriately fashioned jaw bearing abrasive teeth such

that the required profile of teeth are inscribed into the surfaces of the implant. Desirably, the successive teeth of the jaw are incrementally raised in height such that each tooth is only required to remove a small amount of bone (about 0.004" per tooth, to a total depth of 0.015"). In addition, it is preferred that the rake (angle of the teeth) be sufficiently sharp as to allow the implant to bite into the implantation site, without at the same time being so sharp as to be excessively brittle.

In figure 5, figure 5A, there is provided a top view of one side of one embodiment of blades 502 for use in a broach assembly 500 for inscribing teeth into the top 110, bottom 111 or both surfaces of the implant. In outline, there is shown a lock-down handle 501 for clamping the assembly of blades 502 to a base 503. By bringing a mirror image jaw into register with the depicted broach, a space is formed between the opposing teeth 502 at a distance sufficient to accommodate passage of the implant therebetween, provided that the teeth abrade recesses into the top and bottom surfaces of the implant 100. To ensure proper engagement of the blades 502 and the implant 100, there is provided a non-cutting surface 506 for contacting the implant 100 as it is introduced into the broach assembly 500. The non-cutting surface 506 acts as a type of micrometer, forcing the cutting surfaces of the teeth 502 sufficiently apart to properly engage the implant as it passes through the broach assembly 500. In figure 5B, there is provided a side view of an implant mounting device 504 having a "D"-shaped cavity 505 into which a "D"-shaped implant may be fitted for passage through the opposing jaws of the broaching jaw apparatus 500. The resultant implant has the profile shown in figures 1C-1E.

In figures 5C-5E, there is shown an alternate apparatus and method for fashioning the retention teeth in the implant. In figure 5C, there is shown a carriage 510 having an appropriately dimensioned slot 520 for receiving the implant to be grooved. A tensioning screw 530 brings a retention arm 531 into juxtaposition with carriage housing member 532, thereby clamping the implant into position within slot 520. Through carriage housing members 532 and 533, there is aligned a guide-rod 534 for guiding the carriage containing the implant as it is raked across a blade assembly 540, over which said carriage 510 is made to pass. Said guide rod 540 also conveniently acts as a hinge, allowing the carriage 510 to swing upward for implant loading and also permitting the carriage to move down toward the base as the implant surface is cut on each

successive pass of the carriage over said blade assembly 540. The blade assembly 540 is bolted within a base 550 over which said carriage 510 slides. Said base 550 also acts to receive fixation screws 551 and 552 which retain said guide rod 534 in place. A plurality of individual blades 560 are placed in a recess 554 in the base 550 and are maintained in registered position by retention screws 552 passing through retention holes 553 in each blade. Each blade 560 has an initial non-cutting surface 561, which is approximately 0.015" below the cutting surface 562, which in combination with said plurality of blades, forms a flat loading area for implant insertion into said slot 520. Figure 5D provides a side view of one blade 560, while figure 5E provides an end on view of the carriage 510 as it sits above the base 550. Accordingly, the implant is inserted into the slot 520 with the carriage 510 swung up from the base 550. The carriage is then swung down into the starting position with the implant making contact with the non-cutting surfaces 561 of the plurality of blades. The implant is depressed so that it is forced snugly against the non-cutting surface, and then tensioned into place with the retention screw 530. Thereafter, the carriage is slid several times over the base 550 such that the cutting surfaces 562 of the plurality of blades thereby inscribe the desired tooth structure into the top surface, the bottom surfaces or both (after switching the implant around) surfaces of the implant. When the metallic bottom of the carriage comes into contact with the base, the machining of the implant is complete.

In figure 6A-I, there is provided a view of three different cortical bone implants according to this invention having particular geometries by way of example and not limitation. In figure 6A, there is shown an example of an implant 600 which has a height of 7 mm, a width of 11 mm, and a length of 14 mm. In addition, dimensions of various radii of the implant are provided. Note the effect of the "shoulder" 405 of the cutter which produces the a 0.059" radius and indent profile 610 starting at the approximate center of the part and proceeding around to the opposite side of the implant, i.e. around three faces of the implant. In figure 6B, the implant 600 is shown as a side view, and in figure 6C, there is shown a detail view of the teeth. Identical descriptions apply to the 7mmX11mmx11mm views of the implants of figures 6D-6F and the 7mmX14mmx14mm implant of figures 6G-6I.

In figure 7, there is shown a further aspect of this invention in which an implant, either

machined as described above, or prior to said machining, is further machined so as to allow stacking thereof to achieve implants of various heights. Commencing from a blank cortical plug at the stage shown in figure 2D has the advantage that if breakage of the implant occurs during machining, this will likely occur prior to completion of all of machining steps. According to this embodiment of the invention, two implant blanks of known height are selected such that a unitary implant composed of both starting implants can be produced of a new desired height (e.g. a 6 mm high implant may be stacked with a 7 mm high implant to produce a 13 mm implant). Each implant blank is placed in a drill jig, and by means of a drill press or like means, holes are drilled through the implants. With the implants still in the jig, the jig is placed on the table of an arbor press. Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins. In order to encourage bony ingrowth, channels may be cut into the adjacent surfaces of the implants. The embodiment shown in figure 7A is a top view of an implant 700 into which four holes 701-704 have been drilled. In figure 7B, there is shown the juxtaposition of two implants 700A and 700B, with the drilled holes 701-704 in register to receive pins for maintaining the implants in register. In this view, the adjacent surfaces 710A and 710B have not been inscribed with teeth, while the surfaces 711A and 711B have been so inscribed. Based on this disclosure, those skilled in the art will recognize that a number of variations and modifications may be made to stack various forms of bone implants, or to maintain such implants in register with each other. These modifications are to be considered within the scope of this invention.

In a further embodiment of this invention, shown in figure 8, a method for assembling the implant of this invention from component parts is provided. In figure 8A, there is shown an implant 800 composed of two side-by-side halves, 801A and 801B. The two halves of the implant are brought into juxtaposition to form a unitary implant. The two halves may be implanted in juxtaposition, or holes may be formed in each half, and the halves maintained in contact by forcing pins through the holes, in a fashion analogous to that described above for maintaining stacked implants in contact with each other. For this embodiment of the invention, a portion of cortical bone may be harvested from any suitable source of cortical bone. As shown in

figure 8B, a segment, in the form of a block or a column of cortical bone is harvested along the long axis of a long bone, such as the femur, tibia, or fibula. The shape of the bone may be inscribed into the thus-harvested cortical bone by routing, broaching or other means as described herein. The thus-machined cortical bone may then be sectioned into appropriate heights, as needed, to provide the implant halves **801A** and **801B**. Alternate sites for harvesting the cortical bone segment are shown in figures 8B and 8C.

#### 4.4 Manner of Using the Implant

In use, the implant **100** is inserted into a space formed between adjacent vertebrae that are required to be fused. This may be accomplished by the surgeon removing portions of the intervertebral disk, (partial discectomy) and retracting the adjacent vertebrae to allow insertion of an appropriately dimensioned implant. The rear end **105** of the implant is inserted first, and where present, the external feature **120** prevents backing out of the implant. Where no external feature **120** has been inscribed into the top and bottom surfaces of the implant, it may be necessary to affix the implant in position with plate and screw retention systems known in the art. According to this invention, implants are provided having a height of between about 7 and 14 mm, a length of between about 11 and 14 mm and a width of between about 11 and 14 mm. Any permutation or combination of these dimensions may be envisioned, for example (in order of height, length, width): 7x11x11, 8x11x11, etc.; 7x14x14, 8x14x14, etc.; 7x11x14, 8x11x14, etc.

Preferably, the surgeon performing the implantation saves the autologous material and debris produced in the course of the partial discectomy for packing into the canal of the present implant. In addition, or alternatively, the canal may be packed (either during the surgical procedure or the canal may be pre-packed) with osteogenic materials, including but not limited to: allograft bone, autograft bone, demineralized bone, Grafton®, bone powder, bone derivatives, bone morphogenetic protein (purified or recombinant), antibiotic, bioactive glass, hydroxyapatite, bioactive ceramics, or combinations thereof.

Following implantation, the recipient (whether human or animal) is monitored for implant stability and success in fusion. Fusion is achieved over the course of several weeks to

several months, during which time increasing levels of load may be placed on the spine.

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6.0 What is Claimed is:

1           1.     At least one implant consisting substantially of cortical bone, said implant  
2 comprising a canal surrounded by a continuous or discontinuous wall of cortical bone in the  
3 shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top  
4 face and a bottom face, each of which is substantially planar, with said planes being substantially  
5 parallel to each other.

1           2.     The implant of claim 1 consisting substantially of cortical bone, said implant  
2 comprising a canal surrounded by convexly curved anterior cortical bone face and three  
3 substantially rectilinear cortical bone faces unitary with said convexly curved anterior cortical  
4 bone face.

1           3.     The implant of claim 2 which has a substantially "D"-shaped external profile.

1           4.     The implant of claim 2 wherein said canal has a substantially "D"-shape.

1           5.     The implant of claim 2 further having an external feature on said top face, said  
2 bottom face or both.

1           6.     The implant of claim 5 wherein said external feature is at least one groove or  
2 tooth.

1           7.     The implant of claim 6 wherein said external feature is a series of teeth which  
2 angle toward said convexly curved anterior face.

1           8.     The implant of claim 1 wherein an osteogenic composition is packed within said  
2 canal.

1           9.     The implant of claim 8 wherein said osteogenic composition derives from the  
2     intervertebral space into which said implant is inserted, is hydroxyapatite, bone powder, bone  
3     product, bone morphogenetic protein, bioactive glass, bioactive ceramic, or combinations of  
4     these.

1           10.    The at least one implant of claim 1 comprising discontinuous walls consisting  
2     substantially of cortical bone, wherein said discontinuous walls are mirror image halves which, in  
3     combination, form said shape.

1           11.    The at least one implant of claim 1 comprising stacked implants consisting  
2     substantially of cortical bone, said implants comprising a canal surrounded by a continuous or  
3     discontinuous wall of cortical bone in the shape of a circle, an ellipse, or an asymmetric shape,  
4     thereby forming a stacked implant having a top face and a bottom face, each of which is  
5     substantially planar, with said planes being substantially parallel to each other.

1           12.    The at least one implant of claim 11 wherein said stacked implants are pinned to  
2     each other.

1           13.    An implant consisting substantially of at least two shaped cortical bone implants  
2     stacked on top of or adjacent to each other.

1           14.    The implant of claim 13 wherein said shaped cortical bone implants are adapted to  
2     form a unitary implant for implantation into an appropriately dimensioned cavity formed between  
3     adjacent vertebrae.

1           15.    The implant of claim 14 wherein said cortical bone implants are pinned to each  
2     other by cortical bone pins, pins consisting of biocompatible synthetic material or metallic pins.

1           16.    The implant of claim 13 wherein said shaped cortical bone implants are two  
2   mirror image halves of a desired shape.

1           17.    A method of making at least one implant consisting substantially of cortical bone,  
2   said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical  
3   bone in the shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant  
4   having a top face and a bottom face, each of which is substantially planar, with said planes being  
5   substantially parallel to each other, said method comprising:

6           (a) obtaining a plug of bone consisting substantially of cortical bone by using a core  
7           cutter having a central drill bit, thereby forming a canal through the bone plug  
8           obtained with the core cutter;

9           (b) machining the bone plug of step (a) to produce a "washer-shaped" bone plug;

10          (c) machining the canal through the bone plug to form an asymmetric shape therein; and

11          (d) using said asymmetric shape to machine an outside profile of the bone plug.

1           18.    The method of claim 17 wherein said plug of bone is obtained by cutting into the  
2   diaphysis of a long bone and into the intramedullary canal of said long bone to form a bone plug  
3   having a substantially cortical end and an end derived from the wall of the intramedullary canal.

1           19.    The method of claim 18 wherein the end of the plug of bone derived from the  
2   intramedullary canal is machined to form a substantially planar surface to obtain a substantially  
3   "washer-shaped" bone plug composed substantially of cortical bone.

1           20.    The method of claim 19 wherein said canal is formed into an asymmetric shape by  
2   broaching said canal to form said asymmetric shape through the bone plug.

1           21.    The method of claim 20 wherein said asymmetric shape is substantially "D"-  
2   shaped.

1           22.    The method of claim 20 wherein said bone plug having a substantially "D"-  
2 shaped canal is further machined such that the external profile of the bone plug substantially  
3 matches the profile of said canal.

1           23.    The method of claim 20 wherein said further machining comprises contacting the  
2 bone plug with an asymmetrically shaped grinder wheel.

1           24.    The method of claim 20 wherein said further machining comprises mounting said  
2 bone plug on a spindle affixed to an asymmetrically shaped cam and contacting the thus mounted  
3 bone plug with a cutter rotating about a symmetric axis such that the cutter is made to cut more  
4 or less bone as dictated by the shape of said asymmetric cam.

1           25.    The method of claim 24 further comprising stacking said bone plug, either prior to  
2 or after said machining, drilling holes therein, and pinning said stacked bone plugs to each other.

1           26.    A method of making at least one implant consisting substantially of cortical bone,  
2 said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical  
3 bone in the shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant  
4 having a top face and a bottom face, each of which is substantially planar, with said planes being  
5 substantially parallel to each other, said method comprising:

6           (a) cutting a segment of cortical bone;

7           (b) shaping said segment of cortical bone into a symmetric half of the final shape of said  
8 implant comprising a canal surrounded by a continuous or discontinuous wall of  
9 cortical bone, such that when implanted in juxtaposition with a mirror image segment,  
10 an implant is formed having a circular, an elliptical, or an asymmetric shape, a top  
11 face and a bottom face, each of which is substantially planar, with said planes being  
12 substantially parallel to each other; and

13           (c) cutting appropriate lengths of said shaped segment of cortical bone such that said cut  
14 length provides half of an implant having a desired height.

1           27.    The method of claim 17 which further comprises machining an external feature  
2 into the top the bottom or both surfaces of the implant.

1           28.    The method of claim 27 wherein said external feature is machined by passing said  
2 implant through a broach or by repeatedly passing said implant over a plurality of cutting teeth.

1           29.    The method of claim 26 which further comprises machining an external feature  
2 into the top the bottom or both surfaces of the implant.

1           30.    The method of claim 27 wherein said external feature is machined by passing said  
2 implant through a broach or by repeatedly passing said implant over a plurality of cutting teeth.

1           31.    A broach for forming a canal of desired shape in bone which comprises a plurality  
2 of spaced apart rings, wherein the profile of said plurality of spaced apart rings tapers from a first  
3 circular ring to a final ring having said desired shape, said taper allowing for removal by each  
4 consecutive ring of no more than about 0.004" of bone.

1           32.    An apparatus for forming the external profile of a bone plug having an  
2 asymmetric canal, said apparatus comprising (a) a spindle mounted on (b) an asymmetric cam,  
3 wherein the shape of said spindle matches the shape of the asymmetric canal of said bone plug so  
4 as to allow for a tight mounting of said bone plug onto said spindle, and wherein said asymmetric  
5 cam is biased toward (c) a cam follower such that said spindle mounted bone plug is made to  
6 contact (d) a cutter means to an extent dictated by the contact of the cam and cam follower such  
7 that said cutter fashions an external profile onto the bone plug dictated by the shape of said  
8 asymmetric cam.

1           33.    The apparatus of claim 32 comprising:

2           (a) a cross-slide housing a shaft connected to said spindle, to which is also affixed said

asymmetric cam;

(b) a carriage having a slide-way in which said cross-slide translates in a first, Y-plane, said carriage being slideably mounted on a bed such that said carriage translates in a second, X-plane, transverse to said-Y-plane;

(c) a cam-follower which limits the translation of said cross-slide in said Y-plane as said asymmetric cam contacts said cam-follower; and

(d) a stop means which limits the translation of said carriage in said X-plane at a first, predetermined location of said cutter means which is maintained in rotating register with said spindle-mounted implant.

34. The apparatus of claim 33 wherein said cutter means has a "shoulder" thereon defining a radius over which the diameter increases from a first diameter of a cutting surface of said cutter means to a second, greater diameter, of a non-cutting surface of said cutter means.

35. The apparatus of claim 34 wherein the advancement of said implant toward the shoulder of said cutter means is limited by said stop, the positioning of which is dictated by a measuring means which is contacted with said implant prior to formation of said external profile, said measuring means dictating the extent of translation of said implant toward said shoulder of said cutter means.

36. The apparatus of claim 35 wherein said measuring means provides a first and a second stop position for translation of said implant toward said shoulder, such the external profile of said implant may be fully defined by said cutter as said implant is translated toward said first stop position in which contact with said shoulder is prevented, and then, a bevel is formed on one or more edges of said implant by permitting contact of said implant with said shoulder of said cutter means as said implant is further advanced toward said second stop position.

37. An apparatus for forming the external profile of a bone plug having an

2 asymmetric canal, said apparatus comprising (a) a spindle, wherein the shape of said spindle  
3 matches the shape of said asymmetric canal of said bone plug so as to allow for a tight mounting  
4 of said bone plug onto said spindle, and (b) an asymmetrically shaped grinder wheel which may  
5 be brought into contact with said bone plug mounted on said spindle, wherein said grinder wheel  
6 and said spindle are maintained in registered contact with each other via a gear such that the rate  
7 at which the bone plug rotates in relation to the rate of the rotation of the grinder wheel differs  
8 sufficiently to allow abrasion of the surface of the bone plug so as to form an external profile  
9 thereon which is dictated by the asymmetry of said grinder wheel.

1 38. A method for inducing fusion of cervical vertebrae which comprises removing a  
2 portion of the intervertebral disc between the adjacent vertebrae that are to be fused, and inserting  
3 into said space at least one implant consisting substantially of cortical bone; said implant  
4 comprising a canal surrounded by a continuous or discontinuous wall of cortical bone in the  
5 shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top  
6 face and a bottom face, each of which is substantially planar, with said planes being substantially  
7 parallel to each other.

1 39. The method of claim 38 wherein said canal is surrounded by a convexly curved  
2 anterior cortical bone face and three substantially rectilinear cortical bone faces unitary with said  
3 convexly curved anterior cortical bone face, thereby forming an implant having a top face and a  
4 bottom face.

1 40. The method of claim 39 wherein said canal is packed with osteogenic material.

1 41. An implant consisting substantially of cortical bone, said implant having been  
2 prepared by a process comprising:

- 3 (a) obtaining a plug of bone consisting substantially of cortical bone by using a core  
4 cutter having a central drill bit, thereby forming a canal through the bone plug  
5 obtained with the core cutter;

- 6 (b) machining the bone plug of step (a) to produce a "washer-shaped" bone plug;
- 7 (c) machining the canal through the bone plug to form an asymmetric shape therein; and
- 8 (d) using said asymmetric shape to machine an outside profile of the bone plug.

1 42. The implant of claim 41 wherein said plug of bone is obtained by cutting into the  
2 diaphysis of a long bone and into the intramedullary canal of said long bone to form a bone plug  
3 having a substantially cortical end and an end derived from the wall of the intramedullary canal.

1 43. The implant of claim 42 wherein the end of the plug of bone derived from the  
2 intramedullary canal is machined to form a substantially planar surface to obtain a substantially  
3 "washer-shaped" bone plug composed substantially of cortical bone.

1 44. The implant of claim 43 wherein said canal is formed into an asymmetric shape by  
2 broaching said canal to form said asymmetric shape through the bone plug.

1 45. The implant of claim 44 wherein said asymmetric shape is substantially "D"-  
2 shaped.

1 46. The implant of claim 44 wherein said bone plug having a substantially "D"-  
2 shaped canal is further machined such that the external profile of the bone plug substantially  
3 matches the profile of said canal.

1 47. The implant of claim 44 wherein said further machining comprises contacting the  
2 bone plug with an asymmetrically shaped grinder wheel.

1 48. The implant of claim 44 wherein said further machining comprises mounting said  
2 bone plug on a spindle affixed to an asymmetrically shaped cam and contacting the thus mounted  
3 bone plug with a cutter rotating about a symmetric axis such that the cutter is made to cut more  
4 or less bone as dictated by the shape of said asymmetric cam.

1           49.    The implant of claim 48 further comprising stacking said bone plug, either prior to  
2    or after said machining, drilling holes therein, and pining said stacked bone plugs to each other.

1           50.    An implant prepared by a process comprising:

2           (a) cutting a segment of cortical bone;

3           (b) shaping said segment of cortical bone into a symmetric half of the final shape of said  
4           implant comprising a canal surrounded by a continuous or discontinuous wall of  
5           cortical bone, such that when implanted in juxtaposition with a mirror image segment,  
6           an implant is formed having a circular, an elliptical, or an asymmetric shape, a top  
7           face and a bottom face, each of which is substantially planar, with said planes being  
8           substantially parallel to each other; and

9           (c) cutting appropriate lengths of said shaped segment of cortical bone such that said cut  
10          length provides half of an implant having a desired height.

1           51.    The implant of claim 50 which further comprises machining an external feature  
2    into the top the bottom or both surfaces of the implant.

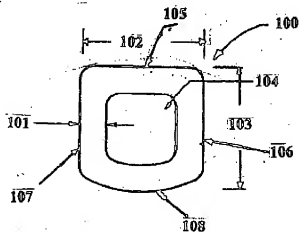
1           52.    The implant of claim 41 which further comprises machining an external  
2    feature into the top the bottom or both surfaces of the implant.

1           53.    An apparatus for inscribing an external feature into a bone implant which  
2    comprises: (a) a base having a recess, said recess housing (b) a plurality of cutting blades having  
3    both a non-cutting upper surface, against which said bone implant may be pressed, and a cutting  
4    upper surface, for inscribing said external feature into said bone implant; said base providing a  
5    sliding surface for a (c) carriage; said carriage being slideably fixed to said base by (d) posts  
6    holding (e) a guide rod; said carriage further having a (e) tensionable slot for receiving said  
7    implant which is loaded into said slot and pushed snugly against said non-cutting upper surface  
8    of said plurality of cutting blades, such that said implant may then be raked across said cutting

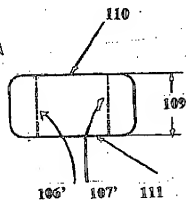
- 9 surface of said plurality of blades to inscribe said external feature therein.

7.0 Abstract of the Disclosure

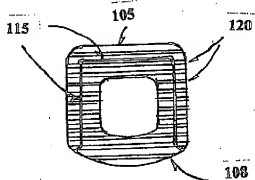
An implant composed substantially of cortical bone is provided for use in cervical Smith-  
5 Robinson vertebral fusion procedures. The implant is derived from allograft or autograft cortical  
bone sources, is machined to form a symmetrically or asymmetrically shaped (e.g. a substantially  
"D"-shaped) implant having a canal running therethrough according to methods of this invention,  
and inserted into the space between adjacent cervical vertebrae to provide support and induce  
fusion of the adjacent vertebrae. Osteogenic materials may be packed into the canal of the  
10 implant to expedite vertebral fusion and to allow autologous bony ingrowth.



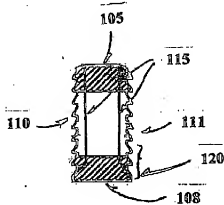
1A



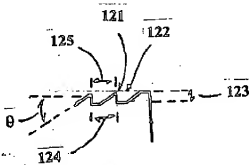
1B



1C



1D



1E

Figure 1

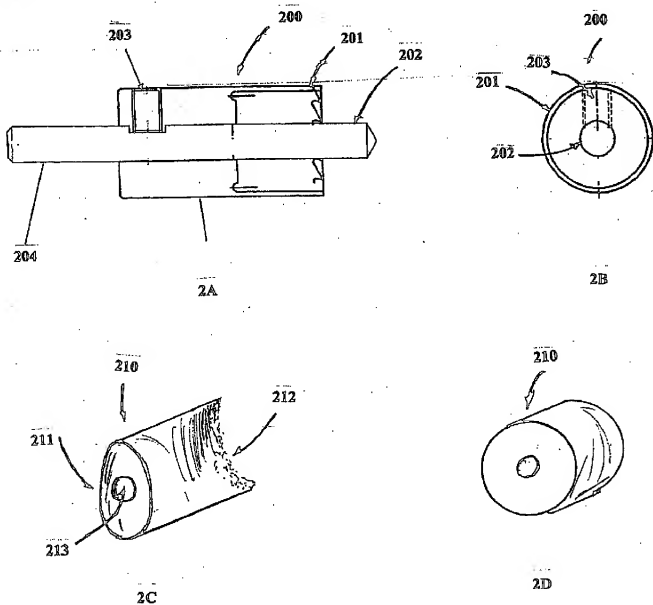
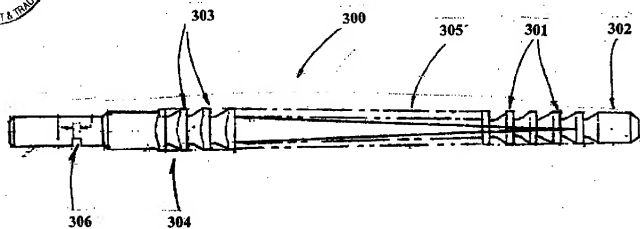
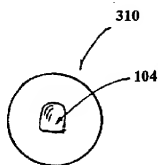


Figure 2



3A



3B

Figure 3

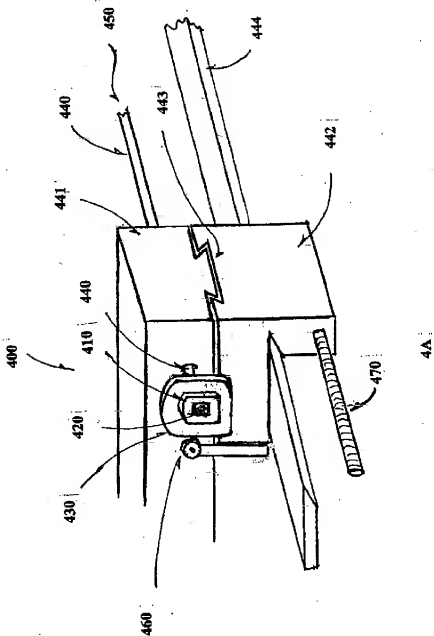


Figure 4

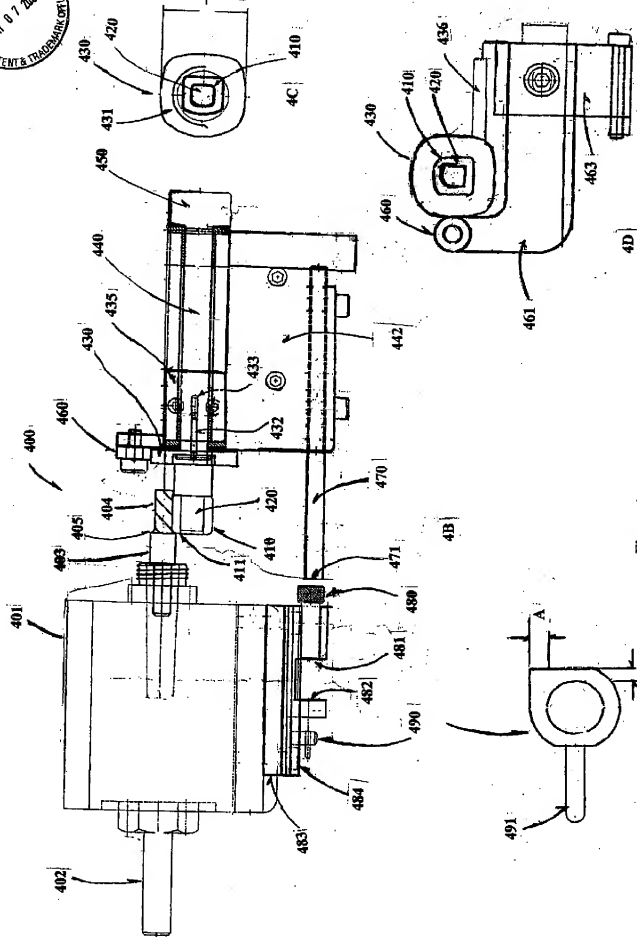


Figure 4

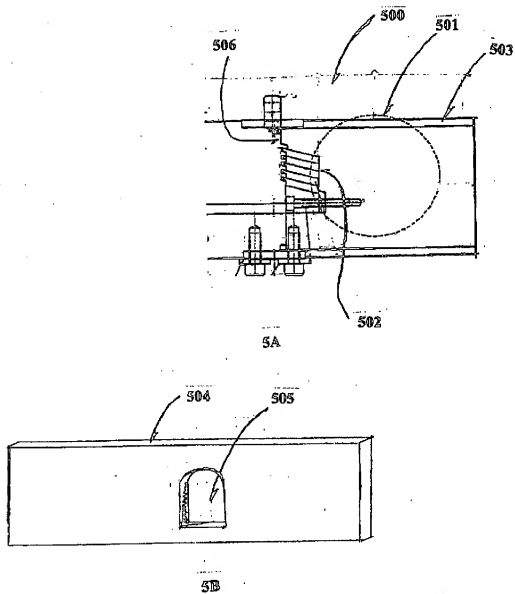


Figure 5

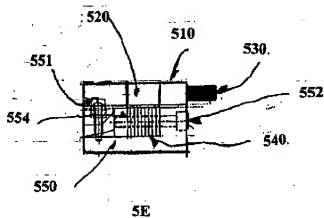
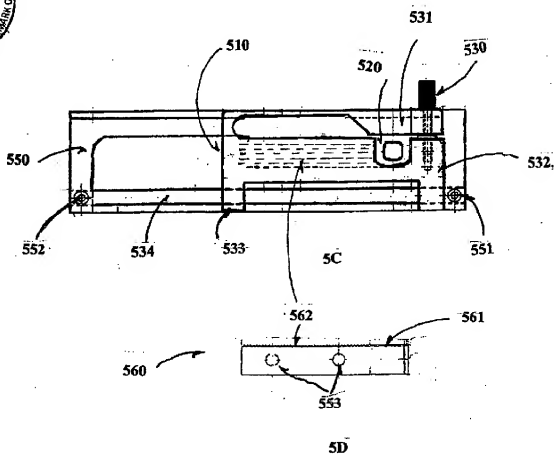
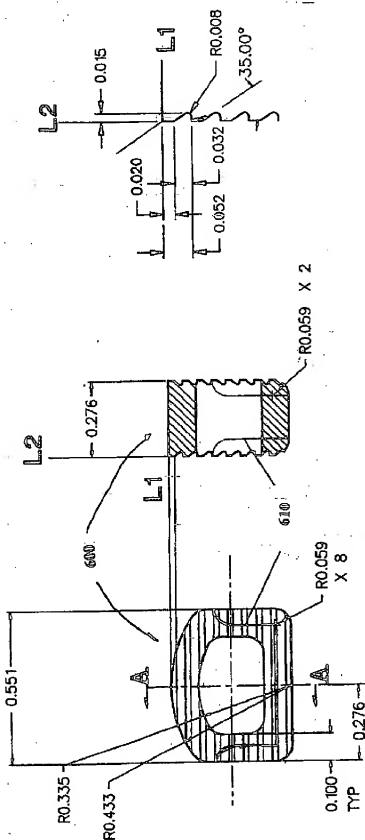


Figure 5



6A.

ਸੰਖਿਆ ੭

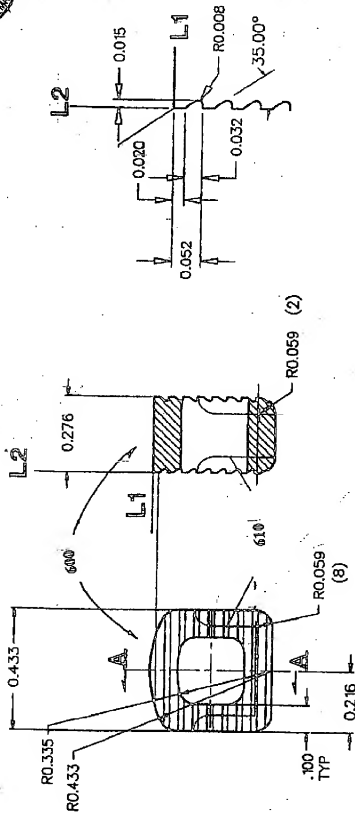


Figure 6

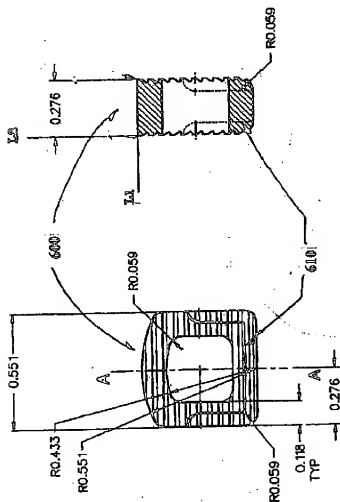
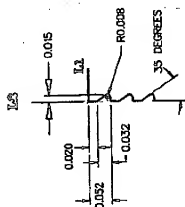


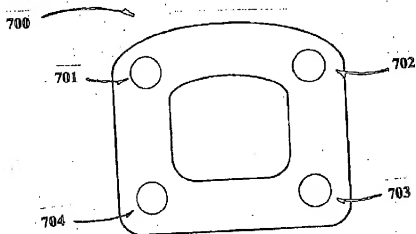
Figure 6



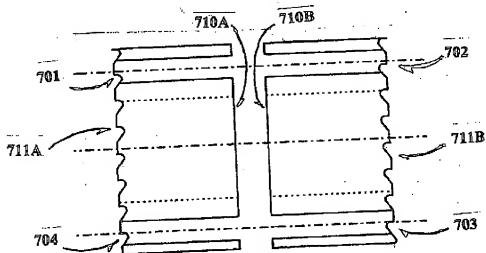
61

6H

6C



7A



7B

Figure 7

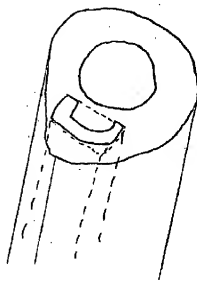
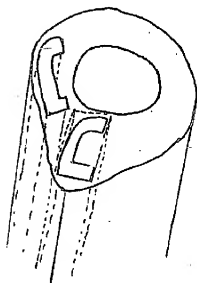
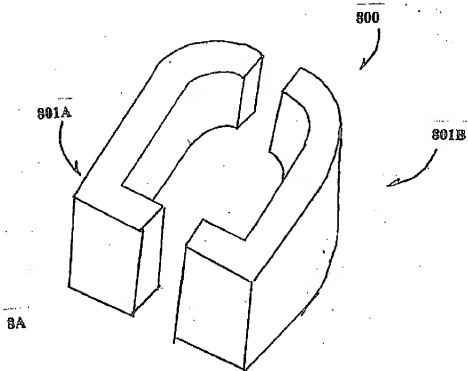


Figure 8



1/14

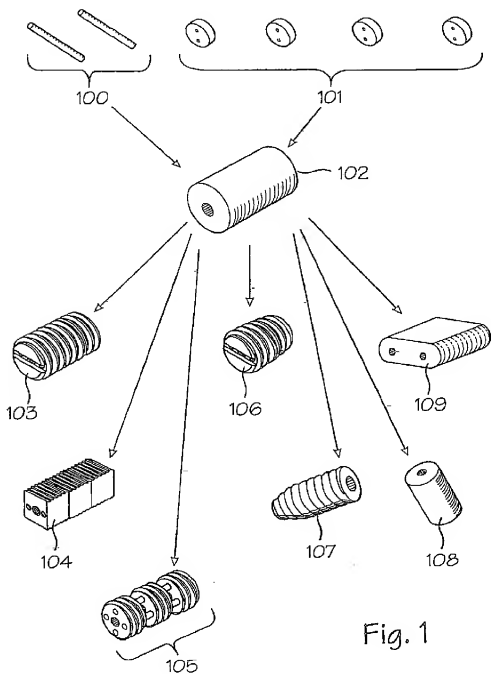


Fig. 1



Title: "Assembled Implant"  
Inventor: Bianchi, John R., et al.  
Application No.: 09/782,594  
Docket No.: RTI 112R/1915-13980US02  
Attorney: Donald J. Pochopien  
Telephone: (312) 775-8133

8/14

Fig. 20A

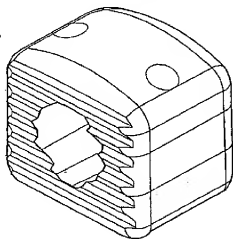


Fig. 20B

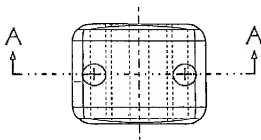


Fig. 20C

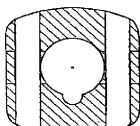


Fig. 20D

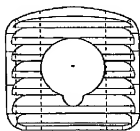


Fig. 20E

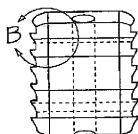


Fig. 20F

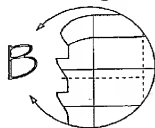


Fig. 20G



# PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional)  
RTI 112A/1915-13980US02



In re the Application of  
Bianchi, John R., et al.

Application Number  
09/782,594

Filed  
February 12, 2001

For  
"Assembled Implant"

Group Art Unit  
3738

Examiner  
Paul B. Prebilit

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

- |  |           |
|--|-----------|
| <input type="checkbox"/> One month (37 CFR 1.17(a)(1))               | \$ _____  |
| <input type="checkbox"/> Two months (37 CFR 1.17(a)(2))              | \$ _____  |
| <input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3)) | \$ 950.00 |
| <input type="checkbox"/> Four months (37 CFR 1.17(a)(4))             | \$ _____  |
| <input type="checkbox"/> Five months (37 CFR 1.17(a)(5))             | \$ _____  |

- ☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the amount shown above is reduced by one-half, and the resulting fee is: \$ \_\_\_\_\_.
- ☒ A check in the amount of the fee is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director has already been authorized to charge fees in this application to a Deposit Account.
- ☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 13-0017. I have enclosed a duplicate copy of this sheet.

- I am the ☐ applicant/inventor
- ☐ assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).
- ☒ attorney or agent of record. Registration Number 32,167
- ☐ attorney or agent under 37 CFR 1.34(a).  
Registration number if acting under 37 CFR 1.34(a) \_\_\_\_\_

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

May 4, 2004

Date

312-775-8000

Telephonic Number

Signature

Donald J. Pochopien, Reg. No. 32,167

Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.



PTO 2037 (11-00)

Approved for use through 10/31/2002. OMB 0651-0032  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## FEE TRANSMITTAL for FY 2004

Patent Fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT | (\$950.00

### Complete if Known

Application Number	09/782,584
Filing Date	February 12, 2001
First Named Inventor	Bianchi, John R., et al.
Examiner Name	Paul B. Preblich
Group Art Unit	3738
Attorney Docket No.	RT112R/1915-13980US02

### METHOD OF PAYMENT

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number: 13-0017  
McAndrews Held & Malloy

- ☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17  
☐ Applicant claims small entity status. See 37 CFR 1.27

2. ☒ Payment Enclosed:  
☒ Check ☐ Credit Card ☐ Money Order ☐ Other

### FEE CALCULATION

#### 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code	Fee Code		
1001 770 2001 385		Utility filing fee	<input type="checkbox"/>
1002 340 2002 170		Design filing fee	<input type="checkbox"/>
1003 530 2003 265		Plant filing fee	<input type="checkbox"/>
1004 770 2004 385		Reissue filing fee	<input type="checkbox"/>
1005 180 2005 80		Provisional filing fee	<input type="checkbox"/>

SUBTOTAL (1) \$950

#### 2. EXTRA CLAIM FEES

Total Claims ☐ -20\*\* = ☐ x ☐ = ☐  
Independent Claims ☐ -3\*\* = ☐ x ☐ = ☐  
Multiple Dependent ☐ = ☐

Large Entity	Small Entity	Fee Description
Fee Code	Fee Code	
2002 18 2202 9		Claims in excess of 20
1201 86 2201 43		Independent claims in excess of 3
1203 200** 2203 145		Multiple dependent claim, if not paid
1204 66 2204 43		**Reissue independent claims over original patent
1205 18 2205 9		**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) \$0

\*\*or number previously paid, if greater. For Reissues, see above

### FEE CALCULATION (continued)

#### 3. ADDITIONAL FEES

Fee Code	Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid
1051 130 2051 65			Surcharge - late filing fee or oath	
1052 50 2052 25			Surcharge - late provisional filing fee or cover sheet	
1053 130 1053 130			Non-English specification	
1812 2,520 1812 2,520			For filing a request for <i>ex parte</i> reexamination	
1804 920* 1804 920*			Requesting publication of SR prior to Examiner action	
1805 1,840* 1805 1,840*			Requesting publication of SR after Examiner action	
1251 110 2251 55			Extension for reply within first month	
1252 420 2252 210			Extension for reply within second month	
1253 950 2253 475			Extension for reply within third month	950.00
1264 1,480 2264 740			Extension for reply within fourth month	
1255 2,010 2255 1,005			Extension for reply within fifth month	
1401 330 2401 165			Notice of Appeal	
1402 330 2402 165			Filing a brief in support of an appeal	
1403 290 2403 145			Request for oral hearing	
1451 1,510 1451 1510			Petition to Institute a public use proceeding	
1452 110 2452 55			Petition to revise - unavoidable	
1453 1,330 2453 665			Petition to revise - unintentional	
1501 1,330 2501 665			Utility issue fee (or reissue)	
1502 480 2502 240			Design issue fee	
1503 610 2503 305			Plant issue fee	
1460 130 1460 130			Petitions to the Commissioner	
1807 60 1807 50			Processing fee under 37 CFR 1.17(a)	
1806 180 1806 180			Submission of Information Disclosure Sheet	
8021 40 8021 40			Recording each patent assignment per property (times number of properties)	
1806 770 2809 365			Filing a submission after final rejection (37 CFR § 1.129(a))	
1810 770 2810 385			For each additional invention to be examined (37 CFR 1.129(b))	
1801 770 2801 365			Request for Continued Examination (RCE)	
1802 900 1802 900			Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$950.00

### SUBMITTED BY

Complete (if applicable)

Name (Print/Type)	Donald J. Pochopien	Registration No. (Attorney or Agent)	32,187	Telephone	312-775-8000
Signature				Date	May 4, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

U.S. PATENT & TRADEMARK OFFICE  
MAY 07 2004

# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/782,594
Filing Date	February 12, 2001
First Named Inventor	Bianchi, John R., et al.
Group Art Unit	3738
Examiner Name	Paul B. Prebille
Attorney Docket Number	RT1112R/1915-13980US02

Total Number of Pages in This Submission 57

## ENCLOSURES (check all that apply)

- |  |  |   |
|--|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input checked="" type="checkbox"/> Fee Attached - \$950.00—<br><input checked="" type="checkbox"/> Amendment and Response Under 37 C.F.R. §1.111 with Exhibit A attached thereto<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input checked="" type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> PTO 1449/08A with references<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application)<br><input checked="" type="checkbox"/> 2 Sheets of Drawings (Sheets 1/14 and 8/14)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Group<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):<br><input checked="" type="checkbox"/> Reply Postcard |
|--|--|---|

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual Name

McAndrews Held & Malloy, Ltd.

Signature

May 4, 2004

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 4, 2004.

Name (Print/type)	Donald J. Pochopien	Registration No. (Attorney/Agent)	32,167
Signature			Date May 4, 2004

## **EXHIBIT 10**



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1470  
Alexandria, Virginia 22313-1470  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490

7590 07/23/2004  
DONALD J. POCHOPJEN  
McANDREWS, HELD & MALLOY, LTD.  
CITICORP CENTER, 34TH FLOOR  
500 WEST MADISON STREET  
CHICAGO, IL - 60661

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/782,594

Applicant(s)

BIANCHI ET AL.

Examiner

Paul B. Preblich

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.  
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-34 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 26-34 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

### ***Drawings***

The drawings are objected to because in Figures 6, 7, 13, 14, 18, 21D, 21E, and 22D, the crosshatching indicates metal not bone components; see MPEP 608.02.

The proposed change to Figure 1 has been approved as had the proposed changed to Figure 20C. However, the other Figures are still objected to because the crosshatching does not clearly show a biochemical component. In particular, not only does a biochemical components have top right to lower left crosshatching, but they also contain horizontal lines and crescent-shaped objects; see the second table of drawing standard in MPEP 608.02.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Upon review of present claims over the subject matter of the various parent applications and related applications, it was determined that claims 26-33 have an effective filing date of February 12, 2001. In particular, claims 27, 31, 32, and 33 have this date because of the "press-fit" limitation is not supported by earlier applications. Support for this limitation can be found in paragraph [0053] of the present application. Claims 26, 28, 29, 30 and 33 have this date because of the preclusion of adhesive, which has support from original claims 28 and 29 of this application. Claims 28-30 have this date because of the "two or more" or "three" connected bone portions in combination with bone pins. Finally, claims 30 and 32 have this date because of the "cancellous" bone portions as claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (US 6,200,347). Anderson anticipates the claim language where the bone portions as claimed are the bone grafts (16 and 17 of Figure 7 or elements 2 and 4 of Figure 1) and the pins of Anderson are threaded and do not contain adhesive (see column 5, lines 29-33); see also column 19, line 62 to column 20, line 36 and column 5, lines 1-8. The interference fit of Anderson with a smaller hole than the pin is considered to be the same as a press fit; see column 5, lines 29-33.

Claims 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by McIntyre (US 4,950,296). McIntyre anticipates the claim language where the first bone portion as claimed is the top half of the cortical bone member (12) of McIntyre, the second bone portion as claimed is the bottom half of the cortical bone portion (12), and the cancellous bone portion is the cancellous plug (20); see Figures 1 and 2 as well as column 2, lines 23-52 where the snug fit is considered to be a press-fit.

Claims 26, 28, 29, 31, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Tormala et al (US 5,084,051). Tormala anticipates the claim language where the first bone portion is layer (2) of Tormala, the second bone portion is layer (1) of Tormala, and the pins as claimed are screws (R) of Tormala. The layers and screws of Tormala are considered to be bone portions because they are for attachment or use with bone and bone repair. This is the same way that a "bone screw" in the art is not necessarily made of bone but rather for use on bone.

#### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3738

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
Art Unit 3738

# **Notice of References Cited**

Application/Control No.  
09/782,594

Applicant(s)/Patent Under  
Reexamination  
BIANCHI ET AL.

Examiner  
Paul B. Prebille

Art Unit  
3738

Page 1 of 1—

## **U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,899,939	05-1999	Boyce et al.	623/16.11
	B	US-6,025,538	02-2000	Yaccarino, III, Joseph A.	128/898
	C	US-5,814,084	09-1998	Grivas et al.	623/23.48
	D	US-6,090,988	07-2000	Grooms et al.	128/898
	E	US-5,676,700	10-1997	Black et al.	623/23.28
	F	US-6,200,347	03-2001	Anderson et al.	623/16.11
	G	US-4,950,296	08-1990	McIntyre, Jonathan L.	623/23.63
	H	US-6,146,420	11-2000	McKay, William F.	623/17.16
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

## **FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

## **NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

## **EXHIBIT 11**



ATTORNEY DOCKET NO. RTI 112R /1915-13980US02

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:

Bianchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

Group Art Unit: 3738

Examiner: Paul B. Prebilic

CERTIFICATE OF MAILING

I hereby certify that this document and all documents referred to herein are being sent by first class mail, postage prepaid, to the Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

November 19, 2004

Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of 07/23/04, for which a response was due 10/23/04, now extended one month to 11/23/04, the Applicants respond as follows:

Amendments to the Claims:

Pages 2-3

Remarks (Including request to remove the  
finality of the rejection over new art):

Pages 4-12

**Amendments to the Claims:**

Please substitute the listing of the claims as provided below for any prior listings:

Claims 1-25 (Cancelled)

26. (previously presented) An assembled bone graft, comprising: a plurality of bone portions layered to form a graft unit, and one or more biocompatible-pins traversing said graft unit for holding said graft unit together, said assembled bone graft does not comprise an adhesive.

27. (previously presented) An assembled bone graft comprising:  
two distinct bone portions of cortical bone, and one or more biocompatible pins, wherein said biocompatible-pins are press fitted into machined holes in said two bone portions to hold together said two bone portions to form said composite bone graft.

28. (previously presented) An assembled bone graft comprising two or more connected, distinct, bone portions forming a graft unit, and two or more cortical bone pins, said two or more connected, distinct, bone portions having holes therein for receiving said two or more cortical bone pins, said cortical bone pins keeping said two or more connected, distinct, bone portions aligned and connected, without an adhesive.

29. (previously presented) The assembled bone graft of claim 28 comprising three connected, distinct, bone portions.

30. (previously presented) The assembled bone graft of claim 28, wherein said two or more connected, distinct, bone portions are selected from the group consisting of: cortical bone and cancellous bone.

31. (previously presented) An assembled bone graft, comprising:  
a first bone portion having one or more holes therein;  
a second bone portion having one or more holes therein aligned with the holes in said first bone portion; and

one or more cortical bone pins press-fitted in said holes for holding said first bone portion in juxtaposition to said second bone portion and forming a graft unit.

32. (currently amended) An assembled bone graft, comprising:

a first cortical bone portion having a hole therein;

a second cortical bone portion having a hole therein, said hole in said second cortical bone portion aligning with said hole in said first cortical bone portion;

a cancellous bone portion press-fitted in the hole between said first cortical bone portion and said second cortical bone portion to form said assembled bone graft.

33. (previously presented) An assembled bone graft, comprising:

a first cortical bone portion having one or more holes therein;

a second cortical bone portion having one or more holes therein aligned with the holes in said first bone portion; and

one or more cortical bone pins press-fitted in said holes for holding said first cortical bone portion in juxtaposition to said second cortical bone portion and forming a graft unit without an adhesive.

34. (previously presented) An assembled bone graft, comprising:

a first bone portion;

a second bone portion provided on said first bone portion to form a graft unit; and

one or more biocompatible pins inserted into said first bone portion and said second bone portion for holding together said graft unit.

35-60. (cancelled)

## REMARKS

The amendment to claim 32 does not add new matter. The amendment to claim 32 merely adds to "said hole" the implied phrase "in said second cortical bone portion." This phrase has support in the immediately preceding phrase in claim 32 and eliminates any confusion as to which "hole" was intended.

### Summary of the Bases for Objection /Rejection

The drawings are objected to because of crossing hatching (FIGs. 6-7, 13-14, 18, 20C, 21D, 21E and 22D) issues.

The Patent Office has assigned an effective filing date of 02/12/01 to claims 26-33.

Claims 26-31 and 33 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.).

Claims 31-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 4,950,296 (McIntyre).

Claims 26, 28, 31, 33 and 34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,084,051 (Tormala).

Each of these bases for objection and/or rejection is addressed in Sections I-VI which follow.

### I. Objection to some of the Drawings

The Patent Office has objected to certain drawings because of cross hatching (FIGs. 6-7, 13-14, 18, 20C, 21D, 21E and 22D) issues. Specifically, the Patent Office objects to FIGs 6-7, 13-14, 18, 20C, 21D, 21E and 22D because the cross-hatching therein indicates "metal" rather than "bone components."

Regarding FIGs. 6-7, 13-14, 18, 20C, 21D, 21E and 22D, the cross hatching is shown as running from top left toward bottom right--like a slash mark. In contrast, the MPEP shows that the cross hatching for a metal runs opposite that of the Applicants, running from top right to bottom left--like a back-slash. Further, the MPEP also shows that for

biochemical components, the correct direction of the hatching is as used by the Applicants running from top left to bottom right. In addition, the hatching for biochemical inventions also includes a series of horizontal dashes and crescent moons. The latter were not included in the applicants' drawings, as they would obscure the details of the drawings. However, the Patent Office is requesting the crescents and horizontal lines. Accordingly, the Applicants co-file with this response substitute FIGs. 6-7, 13-14, 18, 20C, 21D, 21E and 22D, having the crescents and horizontal lines added to clarify that the material shown in the drawings is a biochemical component. Accordingly, this basis for objection has been rendered moot.

## II. Effective Filing Date of Claims 26-33

The Patent Office contends that claims 26-33 are only entitled to the filing date of the present application—February 12, 2001. Specifically, the Patent Office contends that claims 27 and 31-33 have this date because of the “press-fit” limitation. [Official Action at page 2.] In construing the “press-fit” limitation, the Patent Office stated that an “interference fit” and a “snug fit” (of the cited prior art) “is considered to be the same as a press fit.” [Official Action at page 3.]

In response, the Applicants wish to point out that the present invention claims priority to USSN 08/920,630, filed 08/27/97, now abandoned. A copy of this specification is attached as Exhibit A of the Applicants' Response to the Official Action of 11/04/03. This claimed priority application discloses the subject matter of claims 27 and 31-33, directed to an assembled implant comprising two cortical bone pieces that are held together by cortical bone pins that are press fitted into machined holes in the two cortical bone pieces:

**Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins.**

[Exhibit A: USSN 08/920,630 at page 17, lines 10-12; emphasis added in bold.]

\* \* \*

In a further embodiment of this invention, shown in FIG. 8, a method for assembling the implant of this invention from component parts is provided. In FIG. 8A, there is shown an implant 800 composed of **two side-by-side halves**, 801A and 801B. The two halves of the implant are brought into juxtaposition to form a unitary implant. The two halves may be implanted in juxtaposition, or holes may be formed in each half, and the halves **maintained in contact by forcing pins through the holes**, in a fashion analogous to that described above **for maintaining stacked implants in contact with each other**.

[Exhibit A: USSN 08/920,630 at page 17, lines 22-28; emphasis added in bold.]

Thus, the specification of Applicants' claimed priority application does disclose "forcing" or "impelling" pins, i.e., press-fitting pins, into the holes in the two portions of the implant. Accordingly, claims 27 and 31-33 are entitled to the priority filing date of 08/27/97.

As its next basis, the Patent Office alleges that the present application is only entitled to its actual filing date of 02/12/01, based upon the "preclusion of adhesive." The Applicants' priority application, USSN 08/920,630, discloses in the block quotes cited above that "pins" alone were sufficient to form the implant ("**the implants are formed into a unitary body by these pins**") and ("**the halves maintained in contact by forcing pins through the holes**, in a fashion analogous to that described above **for maintaining stacked implants in contact with each other**"). The Patent Office has already determined that reference to "pins" alone is sufficient support for "preclusion of adhesive." Specifically, in relation to Anderson, the Patent Office alleged that "**the pins of Anderson are threaded and do not contain adhesive**," citing to Anderson at col.5, lines1-8 and lines 29-33; and at-col. 19, line 62 to col. 20, line 36. Referring to these sections, the phrase "lack (or preclusion) of adhesive" never expressly appears in Anderson, but as in the Applicants' disclosure, is inferred from the fact that the pins alone were sufficient:

The invention also provides a composite bone graft where the one or more through-holes and the one or more **pins** are round and an inner diameter of a **through-hole** is smaller than a diameter of a pin, to provide an **interference fit between the through-hole and the pin**.

[Anderson at col. 5, lines 29-33; emphasis added in bold.]

Thus, the Applicants' disclosure is equally sufficient with the disclosure in Anderson which the Patent Office has already determined to be sufficient for teaching the lack of need for an adhesive. Moreover, the pins referenced above by Anderson are "pins" and not screws. The common word "screw" never appears in Anderson.

Finally, the Patent Office alleges that claims 30 and 32 have the filing date of 02/12/01 because of the recitation of "cancellous" bone portions. However, the specification of USSN 08/920,630, discloses the presence of the D-shaped cancellous bone plug 310 that fits in the center D-cavity of the implant:

In FIG. 3B, there is provided an end-on view of the **cancellous bone plug 310** after the broaching procedure is completed. As can be seen, the internal canal 104 has been converted from a circular canal into a substantially "D"-shaped canal.

[Exhibit A: USSN 08/920,630 at page 11, lines 7-10; emphasis added in bold.]

The function of the asymmetric D-cavity is to allow any implant to be reproducibly mounted on a jig for machining the exterior surfaces into the appropriate shape, whereupon the cancellous portion can be reinserted.

For all these reasons, claims 26-33 are entitled to the priority filing date of 08/27/97.

### III. 35 U.S.C. § 102(e) over U.S. Pat. 6,200,347 (Anderson)

Claims 26-31 and 33 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.). Anderson has an earliest claimed priority filing date of 01/05/99. Applicants have previously amended claims 26-34 in conformity with the Applicants priority application USSN 08/920,630, filed 08/27/97. Moreover, in Section II herein, the Applicants have cited to those portions of Applicants' claimed priority application USSN 08/920,630 that support claims 26-31 and 33. Accordingly, Anderson, which has an earliest claimed priority date of 01/05/99 is not prior art.

#### IV. 35 U.S.C. § 102(b) over U.S. Pat. 4,950,296 (McIntyre)

Claims 31-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 4,950,296 (McIntyre). Claims 26-30 are free of this cited reference. According to the Patent Office, "McIntyre anticipates the claim language where the first bone portion as claimed is the top half of the cortical bone member (12) of McIntyre, the second bone portion as claimed is the bottom half of the cortical bone portion (12), and the cancellous portion is the cancellous plug (20). . . ." [Official Action at page 3.] The Applicants respectfully disagree.

Each of rejected claims 31-34 is directed to "an assembled bone graft" that includes elements neither taught nor suggested in McIntyre. Specifically, rejected claims 31 and 33 are directed to an assembled bone graft that includes the presence of "one or more **cortical bone pins** press-fitted in said holes for holding said **first bone portion** in juxtaposition to said **second bone portion** and forming a graft unit." In contrast, McIntyre never discloses the use of mentions "cortical bone pins." For this reason alone, claims 31 and 33 are not anticipated by McIntyre.

Claim 34 of the Applicants' invention is directed to "An assembled bone graft, comprising: a **first bone portion**; a **second bone portion** provided on said first bone portion to form a graft unit; and **one or more biocompatible pins** inserted into said first bone portion and said second bone portion for holding together said graft unit." As mentioned in relation to claims 31 and 33, claim 34 is directed to an assembled bone graft that includes "**one or more biocompatible pins.**" McIntyre never discloses the use of a "pin." Rather, McIntyre uses the term "plug" and discloses that the porous cancellous bone "plug" has an "increased surface area that encourages tissue growth, vascularization, and the deposition of new bone":

The **cancellous plug 20** may be obtained from sources rich in cancellous material, such as the knee or the distal condyle. The resulting dowel or plug provides a device that has superior wall strength for support, and **increased surface area that encourages tissue growth, vascularization, and deposition of new bone.** As shown in FIG. 2, the large surface area 22 of cancellous bone is **exposed to or at the outer surface of the dowel to provide optimum conditions for new tissue growth and fusion.** The

dowel may be used in any number of skeletal repair procedures, such as in fusion or securing adjacent bone surfaces together.

[McIntyre at col. 2, line 61 to col. 3, line 4; emphasis added in bold.]

Thus, in contrast to the pin heads that are exposed at the ends of the pins that hold together the portions of the Applicants' implants, McIntyre discloses the use of plugs that have a "large surface area" and perform a very different function – encouraging tissue growth, vascularization, and deposition of new bone. For this reason, claim 34 is not anticipated by McIntyre.

Claim 32 is directed to "[a]n assembled bone graft, comprising: a first cortical bone portion having a hole therein; a second cortical bone portion having a hole therein, said hole in said second cortical bone portion aligning with said hole in said first cortical bone portion; a cancellous bone portion press-fitted in the hole between said first cortical bone portion and said second cortical bone portion to form said assembled bone graft." Thus, on its face, the assembled bone graft of claim 32 has two **separate** bone portions having **separate** holes that are aligned. In contrast, McIntyre has a **single** piece of bone having a **single** hole. Thus, at best, McIntyre discloses only **one** of the **two** bone portions of claim 32 of the Applicants' invention. Moreover, given the thin walls or log shape of the cortical bone segments disclosed in McIntyre, they would not be able to form a stackable bone graft that would be suitable for implantation in a patient. Rather, they are single member non-stacking implants having a cancellous bone plug. For these reason, claim 32 would not be anticipated by McIntyre.

#### VII. 35 U.S.C. § 102(b) over U.S. Pat. 5,084,051 (Tormala)

Claims 26, 28, 31, 33 and 34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,084,051 (Tormala). According to the Patent Office, "Tormala anticipates the claim language where the first bone portion is layer (2) of Tormala, the second bone portion is layer (1) of Tormala, and the pins as claimed are screws (R) of Tormala." [Official Action at page 4; emphasis added in bold.] The Patent Office further contends that "[t]he layers and screws of Tormala are considered to be **bone portions** because

they are for attachment or use with bone and bone-repair. This is the same way that a '**bone screw**' in the art is not necessarily made of bone but rather for use on bone." [Official Action at page 4; emphasis added in bold]. The Applicants respectfully disagree.

The term used in each of claims 26, 28, 31, 33 and 34 is "bone portion" not "bone screw". The interpretation of "bone screw" is irrelevant to the Applicants invention. The Patent Office has attempted to bootstrap an argument on invention consisting of fabricated definitions of terms having no written support in the art. The ordinary meaning of the word "portion" is a part of as greater whole:

**portion** - 1. a **part** or limited quantity of anything. . .

[Exhibit D: Webster's New World Dictionary, Second College Edition, D. Guralink, Ed., Prentice Hall Press, Cleveland Ohio, 1986 at page 1110; emphasis added in bold.]

Thus, the term "bone portion," when given its ordinary meaning, means a part of a bone. Moreover, U.S. Pat. 6,200,347 (Anderson) which is cited by the Patent Office uses the term "bone portion" throughout and as an element in its claims to refer to a part made from recovered bone. See Anderson at col. 11, lines 60-62 ("By the term 'bone' is intended for the purposes of the present invention, bone recovered from any source including animal and human, . . ."). Likewise, the Applicant's priority application discloses that the bone source of the implant is preferably "cortical bone" that may be "allograft" or "autograft:"

An implant composed substantially of **cortical bone** is provided for use in cervical Smith-Robinson vertebral fusion procedures. According to methods of this invention, the implant is derived from **allograft or autograft cortical bone** sources, is machined to form a substantially "D"- shaped implant having a canal into which osteogenic material may be packed.

[Exhibit A: USSN 08/920,630 at page 2, lines 20-23; emphasis added in bold.]

Thus, both the Applicants' invention and the art recognize that the term "bone portion" means a portion of recovered bone. It does not include the combination of polymeric layer and a ceramic layer as disclosed by Tormala. For these reasons, claims 26, 28, 31, 33 and 34 are

not anticipated by the very different invention of Tormala. The allowance of claims 26, 28, 31, 33 and 34 over Tormala is respectfully requested.

#### **VIII. The Finality of This Rejection Should be Withdrawn**

The Patent Office contends that "Applicants' amendment necessitated the new grounds of rejection presented in this Office action." [Official Action at page 4.] The Applicants respectfully disagree. The new basis for rejection under 35 U.S.C. § 102(b) over Tormala is based upon the recitation of "bone portion" in claims 26, 28, 29, 31 and 33-34 which the Patent Office equates to the layers in Tormala. [See the Official Action at page 4 ("The layers and screws of Tormala are considered to be bone portions because they are for attachment or use with bone and bone repair.")]. However, the term "bone portion" was not added by amendment and is the original element in the claims as previously examined. Therefore, this basis for rejection could have been made earlier. The withdrawal of the finality of this rejection is proper and respectfully requested.

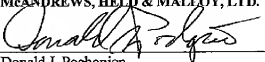
## CONCLUSION

Claims 26-34 are pending. The Applicants have shown that claims 26-33 have an effective filing date of 08/27/97. The rejection of claims 26-31 and 33 under 35 U.S.C. § 102(c) for allegedly being anticipated by U.S. Pat. 6,206,347 (Anderson et al.) has been rebutted. The rejection of claims 31-34 under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 4,950,296 (McIntyre) has been rebutted. The rejection of claims 26, 28, 31, 33 and 34 under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,084,051 (Tornala) has been rebutted. Finally, the Applicants have shown that the finality of this rejection is erroneous because the Patent Office cited new prior art (Tornala) that was not necessitated by the Applicants' amendment.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:



Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8133

Date: November 19, 2004

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SECOND COLLEGE EDITION

**WEBSTER'S  
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DICTIONARY**  
OF THE AMERICAN LANGUAGE

DAVID B. GURALNIK, *Editor in Chief*

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rule 4: axis:

**port-au-Prince** (pôrt'ô prîng'; *Fr.* pôrt ô praws') capital of Haiti; seaport on the Caribbean: pop. 250,000

100

**portiere** (pôr'tî-er) *n.* [Fr. *portière* < *porte*, a door: see **PORT**] a curtain, usually heavy, hung in a doorway

**portion** (pôr'shən) *n.* [ME. < OFr. < L. *portio* (gen. *portionis*), a portion, akin to *harc*, *part*] 1. a



**PORTICO**

 $s < MP_r$ 

where  $\mathbf{1}$  is a



thing, esp. that allotted to a person; share 2. the part of an estate received by an heir 3. the part of a man's money or property contributed by his bride; dowry 4. the part of experience supposedly allotted to a person by fate; one's lot, destiny 5. the part of a meal or quantity of food served to a person; serving; helping —*v.t.* [OFr. *portionner*, *partir*, to divide, separate] 1. to divide into portions 2. to give a portion to; apportion 3. to give a portion to; endow; dower —*SYN.* see FATE, PART —*portion'er* *n.* —*portion'less* *adj.*

**Port Jackson** inlet of the Pacific, in E New South Wales, Australia; harbor of Sydney; 21 sq. mi.

**Port-land** (port'land) 1. [after E. city and port in NW Ore.] at the confluence of the Columbia & Willamette rivers; pop. 366,000 (1960); area 1,230,000 sq. mi. 2. [after Portland, town and island in England] seaport in SW Me., on the Atlantic; pop. 62,000

**portland cement** (*port'land*) a cement made from lime and clay in the form of clumps known as the Isle of Portland, England [sometimes P.] a kind of cement that hardens under water, made by burning a mixture of limestone and clay or similar materials

**Port Louis** capital of Mauritius; seaport on the NW coast; pop. 125,000

**port'ly** (port'li) *adj.* -li-er, -li-est [OFr. *port'ly* + *-ly*] 1. large and heavy in a dignified and stately way 2. stout; corpulent —*port'liness* *n.*

**port-man-tau** (port'man'tau) *n.* [port'man'tau] *n.* pl., -taus, -teaus (-tō) [Fr. *portmanteau* < *porter*, to carry + *man'tau*, a cloak; see PORT & MANTLE] a traveling case or bag; esp., a stiff leather suitcase that opens like a book into two compartments

**portmanteau word** a word that is a combination of two other words in form and meaning (Ex.: *smog*, from *smoke* and *fog*)

**Port Moresby** (port'mōsbi) seaport in SE New Guinea; capital of Papua New Guinea; pop. 77,000

**Porto** (port'ō) *Port. name of OPORTO*

**Porto A-le-gre** (ā'legrē) seaport in S Brazil; capital of Grande São Paulo state; pop. 641,000

**port of call** a port that is a regular stopover for ships, esp. cargo ships

**port of entry** any place where customs officials are stationed to check the entry of people or foreign goods into a country

**Port-of-Spain** (port'āv spān) seaport on NW Trinidad; capital of Trinidad and Tobago; pop. 98,000; also Port of Spain

**Porto-Lo-vo** (port'ōs lō'vō) capital of Benin; seaport on the Gulf of Guinea; pop. 190,000

**Porto-Ri-co** (port'ōs ri'kō) former name of PUERTO RICO

**Porto-Ri-co** (port'ōs ri'kō) former name of PUERTO RICO

**Port Phillip Bay** inlet of Bass Strait, in S Victoria, Australia; harbor of Melbourne; 762 sq. mi.

**port'rait** (port'rait) *n.* (pl. *portraits*) *n.* [OFr. *portrait* < *portray*] 1. orig., a drawn, painted, or carved picture of something 2. a representation of a person, esp. of his face, drawn, painted, photographed, or sculptured 3. a descriptive, dramatic portrayal, etc. of a person

**port'rait-lit** (-lit) *n.* a person who makes portraits

**port'rait-ure** (port'rait-ur) *n.* [ME. *portraiture* < MFr. *portrait* < *portr*, to draw forth < *port*, forth + *trahere*, to draw] 1. to make a picture or portrait of; depict; delineate 2. to make a word picture of; describe graphically 3. to play the part in a play, movie, etc. —*port'ray'able* *adj.*

**port'ray'er** *n.* 1. the act of portraying 2. a portrait; description; representation

**port'tress** (port'tress) *n.* a woman porter (doorkeeper)

**Port Royal** town and city on the entrance to Kingston harbor; the original town, former capital, was destroyed by an earthquake in 1692

**Port Sa-Id** (sā'id) seaport in NE Egypt, at the Mediterranean end of the Suez Canal; pop. 244,000

**Port-Sa-lut** (pōr'sā lōt) (Fr. *pōr sā lōt*) *n.* same as Port au Salut

**Portsmouth** (pōr'tsmūth) 1. seaport in Hampshire, S England, on the English Channel; pop. 218,000 2. [after Portsmouth] seaport in SE Va., on Hampton Roads; pop. 165,000; see NORFOLK

**Port Sudan** seaport in NE Sudan, on the Red Sea; pop. 37,000

**Port-u-gal** (pōr'tēgal) *adj.* *Port. port'gō* (lō'gō) country in SW Europe, on Atlantic; 34,308 sq. mi.; pop. 8,283,000 (with the Azores & Madeira, 35,509 sq. mi.; pop. 9,228,000); cap. Lisbon

**Port-u-guese** (pōr'tēgēs) *adj.* of Portugal, its people, their language, or culture —*n.* pl. -gūez a native or inhabitant of Portugal 2. the Romance language spoken in Portugal and Brazil

**Portuguese East Africa** *alt. name of MOZAMBIQUE*, when it was a Portuguese territory

**Portuguese Guinea** former name of GUINEA-BISSAU

**Portuguese India** former Portuguese overseas territory consisting of three enclaves in India; see GOA

**Portuguese man-of-war** any of several large, colonial, warm-sea siphonophores (genus *Physalia*) having a large, bladderlike sac, with a saillike structure on top, which enables them to float on the waves and long, dangling tentacles that have powerful stinging cells

**Portuguese Timor** former Portuguese territory in the Malay Archipelago, consisting principally of the E half of Timor since 1976, a province of Indonesia

**Portuguese West Africa** *alt. name of ANGOLA*, when it was a Portuguese territory

**por-tu-lac'a** (pōr'tē-lāk'a) *n.* [ModL. < L. *portulaca* < *portus*, dim. of *portus*, dock (see PORT) + *lac'a*, the doorknob opening of the seed capsule; a fleshy annual plant (*Portulaca grandiflora*) of the purslane family with yellow, pink, or purple flowers]

1. position 2. positive 3. possessive

**po-sa-da** (pō sā'dā) *n.* [Sp. < fem. of *porado*, pop. of *poro*, to lodge < L. *pausare*, to stop < *pausa*, a PAUSE] in Spanish-speaking countries 1. an inn 2. a Christmas festival marked by a candlelight procession

**poset** (pōz) *vt.* posed, *pos'ing* [ME. *posen* < OFr. *poser*, to put in position < L. *ponere*, to place, put + *-et*, to put, rest < L. *posui*; see POSUI] meaning and form altered after L. *positus*, pp. of *ponere*, to place, put; see POSITION] 1. to put forth; assert (a claim, argument, etc.) 2. to put forth or propose (a theory, etc.) 3. to put (a model, photographic subject, etc.) in a certain position or attitude —*vt.* 1. to assume a certain position or attitude, as in modeling for an artist 2. to strike attitudes for effect; attitude 3. to pretend to be what one is not; set oneself up (as) (*to pose as an officer*) —*n.*

[Fr. < the *v.*] 1. a bodily attitude, esp. one held for or by an artist, photographer, etc. 2. an attitude of behaving or speaking (as) (*he posed as a saint*)

**POSE** —*pose* refers to an attitude or manner that is assumed for the effect that it will have on others (her generosity is a mere pose); *pose* is used of a specific kind of act, posture, or intended obviously to impress others (an *eloquent* pose of speech); a *mannerism* is a peculiarity in behavior, speech, etc. (often especially an affectation) that has become a habit and is conscious (his *mannerism* of raising one eyebrow in surprise); *airs* (she's always putting on airs)

**pose'** (pōz) *vt.* posed, *pos'ing* [aphetic for APPOSE, OPPOSE] 1. [Obs.] to question 2. to puzzle or disconcert, as by an awkward or questionable question

**PO-see-don** (pō sī'dn, pā-) [L. < Gr. *Posidon*] Gr. myth. god of the sea and of horses; identified with the Roman god Neptune

**Pos-er** (pō'ser) *Ger. name of POZNAN*

**pos'er** (pō'ser) *n.* a person who poses; esp., a poseur

**pos'er** (pō'ser) *n.* a baffling question or problem

**pos'it** (pō'sit) *n.* 1. a person's attitude or attitude or manners merely for their effect upon others

**posh** (pōsh) *adj.* [prob. < obs. Brit. slang *posh*, a dandy < ?] [Colloq.] luxurious and fashionable; elegant —*poshly* *adv.* —*posh'ness* *n.*

**Pos-han** (pō'shān, bō'shān) same as TZUO

**pos-it** (pō'sit) *vt.* < L. *ponere*; see P. 1. to set in place or position; situate 2. to set down or assume (an act, position, etc.)

**pos-it-ion** (pō'sh'ān) (*pos'ish'ān*) (*pos'ish'ān*) *n.* [L. *positio* < *ponere*, to place < *ponere* < *posui*, to place < *ponere*, whence L. *ob*, from, away + *ponere*, to place] 1. the position or placing of a proposition; affirmation 2. the manner in which a person or thing is placed or arranged; attitude; posture; disposition 3. one's attitude toward society, business, etc.; stand (his *pos* in foreign aid) 5. the place where a person or thing is, esp. in relation to others; location; situation; site (the ship's *pos*) 6. the usual or proper place of a person or thing (the *pos* of the lawyer) 7. a location or condition in which one has the advantage (to jockey for *pos*) 8. a strategic military site 9. a person's relative place, in a society, race, status 10. a place high in society, business, etc. (a man of *pos*) 11. a post of employment; office; job (to apply for a teaching position) 12. Finance the long or short commitment of a man in a business or security

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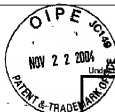
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Examiner Name	Paul B. Prebille
Attorney Docket Number	RTI 112R/1915-13980US02

**ENCLOSURES (check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input checked="" type="checkbox"/> Fee Attached - \$110.00	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input checked="" type="checkbox"/> Amendment and Response Under 37 C.F.R. §1.116	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input checked="" type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Return-Receipt Postcard
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	<input type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application	Remarks	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm	McAndrews Held & Malloy, Ltd.
Signature	<i>Donald J. Pochpien</i>
Printed Name	Donald J. Pochpien, Reg. NO. 32,167
Date	November 19, 2004

**CERTIFICATE OF MAILING**

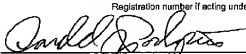
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 11/19/2004

Name (Print/type)	Donald J. Pochpien	Registration No. (Attorney/Agent)	32,167
Signature	<i>Donald J. Pochpien</i>	Date	11/19/2004



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PTO/SB/22 (10-04)  
Approved for use through 7/31/2008. OMB 0581-0031  
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

<b>APPLICATION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2005 (fees effective on or after October 1, 2004)</b>		Docket Number (Optional) RTI 112R/1915-13990US02	
Application Number 09/782,594		Filed February 12, 2001	
For "Assembled Implant"			
Art Unit 3738		Examiner Paul B. Preblich	
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.			
The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):			
	<u>Fee</u>	<u>Small Entity Fee</u>	
<input checked="" type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$110	\$55	\$110.00
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$430	\$215	\$
<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$980	\$490	\$
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1530	\$765	\$
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2080	\$1040	\$
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.			
<input checked="" type="checkbox"/> A check in the amount of the fee is enclosed.			
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.			
<input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.			
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>13-0017</u> . I have enclosed a duplicate copy of this sheet.			
<b>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</b>			
I am the <input type="checkbox"/> applicant/inventor.			
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71			
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).			
<input checked="" type="checkbox"/> attorney or agent of record. Registration Number <u>32,167</u>			
<input type="checkbox"/> attorney or agent under 37 CFR 1.34.			
Registration number if acting under 37 CFR 1.34, _____.			
 Signature		November 19, 2004 Date	
Donald J. Pochoplen, Reg. No. 32,167		312-775-8000	
Typed or printed name		Telephone Number	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			

This collection of information is required by 37 CFR 1.136(e). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1459, Alexandria, VA 22313-1459.

11/23/2004 HGBREX1 00000027 09782594 you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/21 (08-00)  
Approved for use through 10/31/2002  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
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AF  
1615  
JW

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	09/782,594
	Filing Date	02/12/2001
	First Named Inventor	Blanchi, et al.
	Group Art Unit	1615
	Examiner Name	Pau. B. Prebilit
Total Number of Pages in This Submission	19	Attorney Docket Number: RTI 112R/1915/13980US02

**ENCLOSURES (check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> PTO 1449/08A with 2 references <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) ( sheets) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Return-Receipt Postcard <input type="checkbox"/> Other Enclosure(s) (please identify below):		
<table border="1"><tr><td>Remarks</td><td></td></tr></table>			Remarks	
Remarks				

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual Name	Donald J. Pochopien, Reg. No. 32,167 McAndrews, Held & Malloy, Ltd.
Signature	
Date	October 27, 2004

**CERTIFICATE OF MAILING**

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Name (Print/Type)	Donald J. Pochopien	Registration No. (Attorney/Agent)	32,167
Signature		Date	10/27/2004

## **EXHIBIT 12**



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490
7590 12/08/2004				
DONALD J. POCHOPIEN McANDREWS, HELD & MALLOY, LTD. CITICORP CENTER, 34TH FLOOR 500 WEST MADISON STREET CHICAGO, IL 60661				
EXAMINER PREBILIC, PAUL B				
ART UNIT 3738		PAPER NUMBER		

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/782,594

Applicant(s)

BIANCHI ET AL. 

Examiner

Paul B. Preblich

Art Unit

3738

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☒ The proposed amendment(s) will not be entered because:  
(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *The proposed change to claim 32 would require additional consideration and/or search.*

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 26-34

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_  
10. ☐ Other: \_\_\_\_\_

  
Paul B. Preblich  
Primary Examiner

## **EXHIBIT 13**



ATTORNEY DOCKET NO. RT1112R /1915-13980US02

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:

Bianchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

Group Art Unit: 3738

Examiner: Paul E. Prebille

CERTIFICATE OF MAILING

I hereby certify that this document and all documents referred to herein are being sent by first class mail, postage prepaid, to the Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

December 09, 2004

Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants

TRANSMITTAL OF SUBSTITUTE DRAWINGS REQUESTED BY THE EXAMINER

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

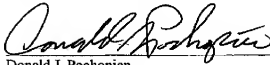
In response to the Official Action of 07/23/04, for which a response was due 10/23/04, previously extended one month to 11/23/04, and now extended a second month to 12/23/04, the Applicants attach hereto six (6) Substitute Sheets of Drawings (Sheets 3, 5, 6, 8, 9, and 10/14).

The Patent Office has objected to certain drawings because of cross hatching on FIGs. 6-7, 13-14, 18, 20C, 21D, 21E and 22D. The substitute sheets attached hereto removed all cross-hatching on FIGs 6-7, 13-14, 18, 20C, 21D, 21E and 22D. No new matter has been added. Accordingly, this basis for objection has been rendered moot.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:


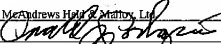
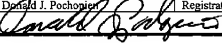


Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8133

Date: December 09, 2004

J:\open\Jip\Regeneration Technologies\USPTO\13980US02\TRANS SUB DRAWINGS.doc

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		Application Number		09/782,594					
		Filing Date		February 12, 2001					
		First Named Inventor		Blanchi, John R., et al.					
		Art Unit		3738					
		Examiner Name		Paul B. Probitic					
Total Number of Pages in This Submission		10		Attorney Docket Number		RTI 112R/1915-13980US02			
<b>ENCLOSURES (check all that apply)</b>									
<input type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached - \$340.00 <input checked="" type="checkbox"/> Transmittal of Substitute Drawings Requested by The Examiner <input checked="" type="checkbox"/> 6 Substitute Sheets of Drawings (Sheets 3, 5, 6, 8-9, 10/14) <input checked="" type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD		<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Return-Receipt Postcard <input type="checkbox"/> Other Enclosure(s) (please identify below):		Remarks			
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>									
Firm		McAndrews Held & Muthox, LLP							
Signature									
Printed Name		Donald J. Pochopien, Reg. No. 32,167							
Date		December 9, 2004							
<b>CERTIFICATE OF MAILING</b>									
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Name (Print/type)		Donald J. Pochopien		Registration No. (Attorney/Agent)		32,167			
Signature						Date		12/09/2004	



Title: "Assembled Implant"  
 Inventor: Bianchi, John R., et al.  
 Application No.: 09/782,594  
 Docket No.: RTI 112R/1915-13980US02  
 Attorney: Donald J. Puchopien  
 Telephone: (312) 775-8133

3/14

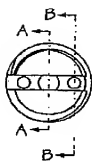
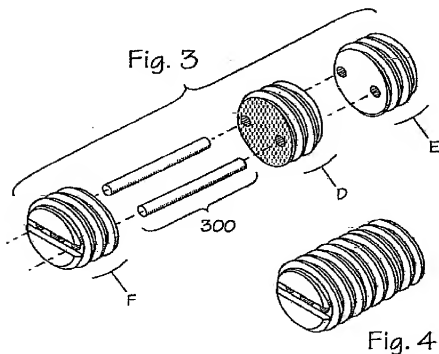


Fig. 5

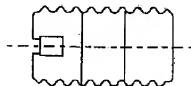


Fig. 6

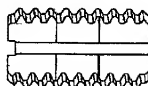


Fig. 7

5/14

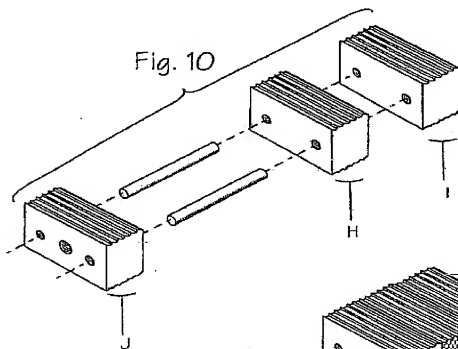


Fig. 11

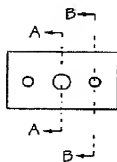
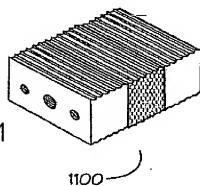


Fig. 12



Fig. 13

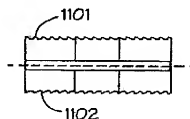
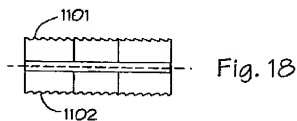
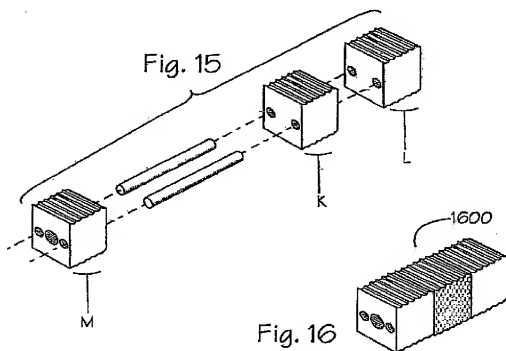


Fig. 14

6/14



8/14

Fig. 20A

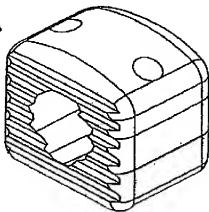


Fig. 20B

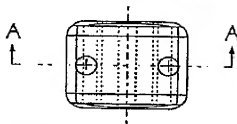


Fig. 20C

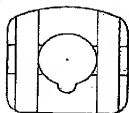


Fig. 20D

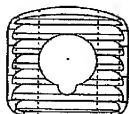


Fig. 20E

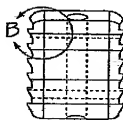


Fig. 20F

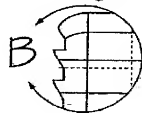
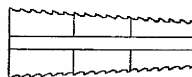
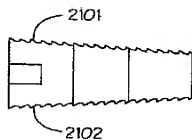
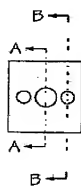
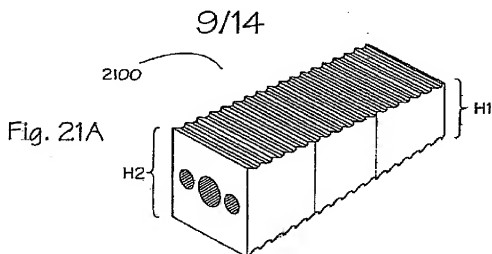


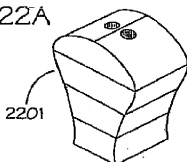
Fig. 20G





10/14

Fig. 22A



2201

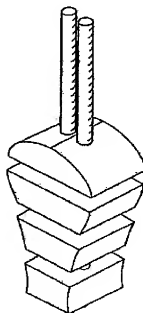


Fig. 22C

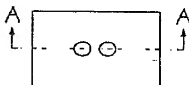


Fig. 22B

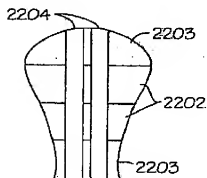


Fig. 22D

Fig. 22E

## **EXHIBIT 14**



## UNITED STATES PATENT AND TRADEMARK OFFICE

30

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490
7590 01/04/2005				
DONALD J. POCHOPIEN McANDREWS, HELD & MALLOY, LTD. CHICORP CENTER, 34TH FLOOR 500 WEST MADISON STREET CHICAGO, IL. 60661				
EXAMINER PREBILIC, PAUL B				
ART UNIT 3738		PAPER NUMBER		

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/782,594

Applicant(s)

BIANCHI ET AL.

Examiner

Paul B. Prebille

Art Unit

3738

—The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED 13 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☒ The proposed amendment(s) will not be entered because:  
(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ they raise the issue of new matter (see Note below);  
(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See *Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 26-34.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☒ The drawing correction filed on 13 December 2004 is a) ☐ approved or b) ☒ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_  
10. ☐ Other: \_\_\_\_\_

  
Paul B. Prebille  
Primary Examiner

Continuation of 2. NOTE: The proposed drawing changes are not approved because the original specification described these figures as cross-sectional views; see page 11 of the original specification, for example. Removing the cross-hatching, as proposed, makes these figures appear to be plan views since cross-hatching is always used with cross-sectional views. For this reason, the proposed changes to the drawings may implicitly add new matter to the specification.

## **EXHIBIT 15**



ATTORNEY DOCKET NO. RTI 112R /1915-13980US02

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:

Bianchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

Group Art Unit: 3738

Examiner: Paul B. Prebille

CERTIFICATE OF MAILING

I hereby certify that this document and all documents referred to herein are being sent by first class mail, postage prepaid, to the Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

January 20, 2005

Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants

REQUEST FOR CONTINUED EXAMINATION UNDER 37 C.F.R. § 1.114

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of 07/23/04 finally rejecting all claims, for which a response was due 10/23/04, now extended three months to 01/23/05, a first month having already been paid, Applicant Request Continued Examination (RCE) under 37 C.F.R. § 1.114. As part of Applicants' RCE, Applicants request entry of the amendments and arguments provided in the Applicants' Request for Reconsideration under 37 C.F.R. § 1.116 filed 10/29/04.

Applicants cofile a Submission of Corrected Drawings in response to an Advisory Action dated 01/04/05.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:



Donald J. Pochopien

Registration No. 32,167

Attorney for Applicants

500 West Madison Street, 34<sup>th</sup> Floor

Chicago, Illinois 60661

(312) 775-8133

Date: January 20, 2005

J:\open\DJp\Regeneration Technologies\USPTO\13980US02\Resp 1.116.doc



RCEX

PTO/SB/21 (09-04)

Approved for use through 7/31/2006

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	09/782,594	
	Filing Date	February 12, 2001	
	First Named Inventor	John R. Bianchi	
	Art Unit	3738	
	Examiner Name	Paul B. Preblich	
Total Number of Pages in This Submission	14	Attorney Docket Number	13980US02

**ENCLOSURES (check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input checked="" type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Return-Receipt Postcard <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks		(1) Request For Continued Examination Under 37 C.F.R. Section 1.114; (2) Second Transmittal of Substitute Drawings Requested by the Examiner

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**


Firm	McAndrews Held & Malloy, Ltd.
Signature	
Printed Name	Donald J. Pochopien
Date	January 20, 2005

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 01/20/2005

Name (Print/type)	Donald J. Pochopien	Registration No. (Attorney/Agent)	32,167
Signature		Date	01/20/2005

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<p><i>Effective on 12/09/2004.</i> Fees pursuant to the consolidated Appropriates Act, 2005 (H.R. 4318).</p> <h2 style="text-align: center;">FEE TRANSMITTAL for FY 2005</h2>		<p><b>Complete If Known</b></p>					
		Application Number	09/782,594				
		Filing Date	February 12, 2001				
		First Named Inventor	John R. Bianchi				
		Examiner Name	Paul B. Preblich				
		Art Unit	3738				
		Attorney Docket No.	-13980US02				
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27							
<b>TOTAL AMOUNT OF PAYMENT</b> (\$) 1,700.00							
<b>METHOD OF PAYMENT</b> (check all that apply)							
<input checked="" type="checkbox"/> Check <input type="checkbox"/> Credit Card <input type="checkbox"/> Money Order <input type="checkbox"/> None <input type="checkbox"/> Other (please identify): _____							
<input checked="" type="checkbox"/> Deposit Account Deposit Account Number: 13-0017 Deposit Account Name: McAndrews Held & Malloy For the above-identified deposit account, the Director is hereby authorized to (check all that apply)							
<input type="checkbox"/> Charge Fee(s) indicated below <input type="checkbox"/> Charge Fee(s) indicated below, except for the filing fee							
<input checked="" type="checkbox"/> Charge any additional fee(s) or underpayments of fees(s) <input checked="" type="checkbox"/> Credit any overpayments under 37 CFR 1.16 and 1.17							
<b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.							
<b>FEE CALCULATION</b>							
<b>1. BASIC FILING, SEARCH, AND EXAMINATION FEES</b>							
	FILING FEES		SEARCH FEES	EXAMINATION FEES			
Application Type	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fees Paid (\$)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	
							Small Entity
<b>2. EXCESS CLAIM SIZE FEES</b>							
<b>Fee Description</b>							Fee (\$)
Each claim over 20, or for Reissues, each claim over 20 and more than in the original patent							50
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent							200
Multiple dependent claims							360
							180
							Small Entity
<b>Total Claims</b>							Fee (\$)
-20 or HP x =							Fee Paid (\$)
HP = highest number of total claims paid for, if greater than 20							
<b>Indep. Claims</b>							Fee (\$)
-3 or HP x =							Fee Paid (\$)
HP = highest number of independent claims paid for, if greater than 3							
<b>3. APPLICATION SIZE FEE</b>							
If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
<b>Total Sheets</b>				<b>Extra Sheets</b>			
-100				/50 (round up to a whole number) x =			
							Fee Paid (\$)
<b>4. OTHER FEE(S)</b>							
Non-English Specification, \$130 fee (no small entity discount)							
★ Request For Continued Examination-\$790 and Three-Month Extension of Time (1 Month Already Paid)-\$910							1,700
<b>SUBMITTED BY</b>							
Signature		Registration No. (Attorney/Agent)		32,167		Telephone (312)775-8000	
Name (print/type)		Donald J. Pochopien		Date		01/20/2005	



ATTORNEY DOCKET NO. RT1 112R /1915-13980US02

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of: )  
Bianchi, John R., *et al.* )  
Serial No.: 09/782,594 )  
Filed: February 12, 2001 )  
For: "Assembled Implant" )  
Group Art Unit: 3738 )  
Examiner: Paul B. Prebille )

CERTIFICATE OF MAILING

I hereby certify that this document and all documents referred to herein are being sent by first class mail, postage prepaid, to the Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

January 20, 2004

Donald J. Pochoplen  
Registration No. 32,167  
Attorney for Applicants

SECOND TRANSMITTAL  
OF SUBSTITUTE DRAWINGS REQUESTED BY THE EXAMINER

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

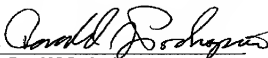
In response to the Advisory Action of 01/04/05, wherein the Patent Office objected to the lack of cross-hatching in FIGs 6-7, 13-14, 18, 20C, 21D, 21E and 22D, Applicants attach hereto six (6) Substitute Sheets of Drawings (Sheets 3, 5, 6, 8, 9, and 10/14) to be substituted for the originally filed Sheets 3, 5, 6, 8, 9, and 10 of 14.

The attached Substitute sheets of Drawings added appropriate cross-hatching to the cross-sectional drawings shown in FIGs 6-7, 13-14, 18, 20C, 21D, 21E and 22D. The appropriate cross hatching is as shown in the attached page of the MPEP at §608-02 for biochemical materials. No new matter has been added. Accordingly, this basis for objection to the drawings has been rendered moot.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

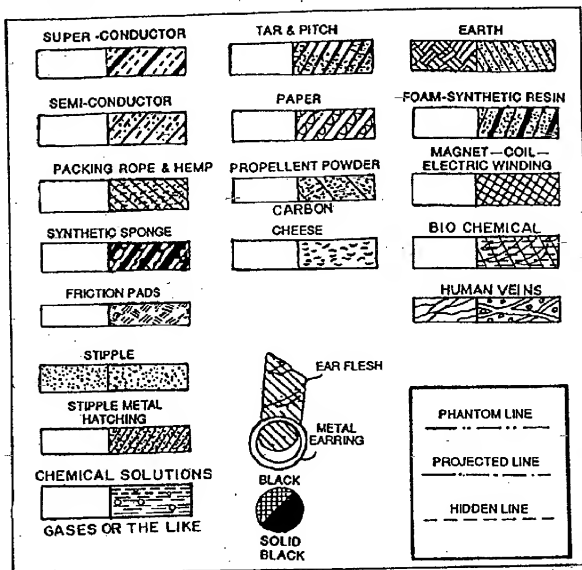
By: \_\_\_\_\_



Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8133

Date: January 20, 2005

J:\open\DJp\Regeneration Technologies\USPTO\13980US02\2<sup>ND</sup> TRANS SUB DRAWINGS.doc





3/14

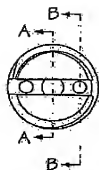
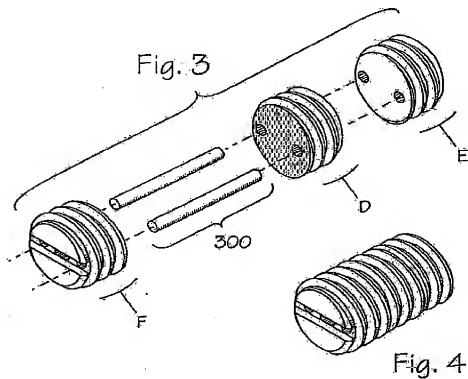


Fig. 5



Fig. 6

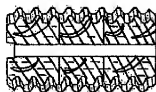


Fig. 7



TITLE: Assembled Implant  
 INVENTOR: Bianchi, et al.  
 APPLICATION NO.: 09/782,584,  
 CONF. NO. 9490; DOCKET NO. 13980US02  
 ATTORNEY: OJP, PHONE: 312-775-8000

5/14

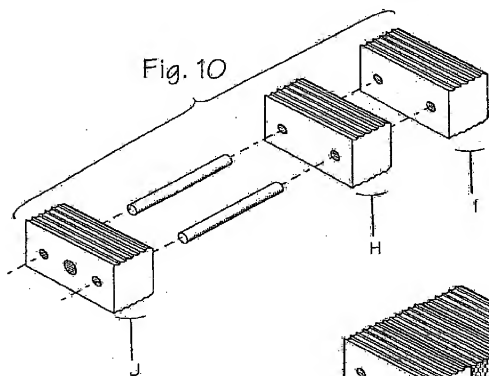


Fig. 11

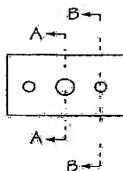
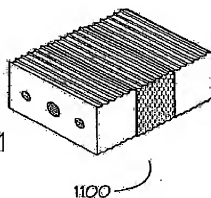


Fig. 12



Fig. 13

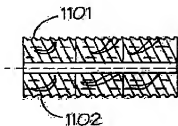
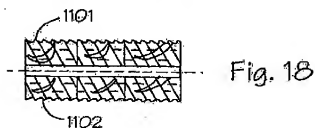
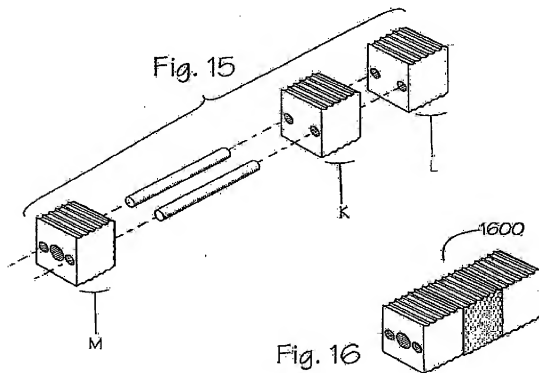


Fig. 14



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TITLE: Assembled Implant  
INVENTOR: Bianchi, et al  
APPLICATION NO.: 09/782,594,  
CONF. NO. 9490; DOCKET NO. 13980US02  
ATTORNEY: DJP, PHONE: 312-775-8000

8/14

Fig. 20A

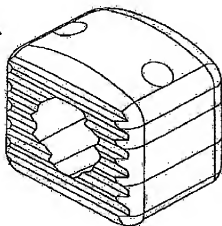


Fig. 20B

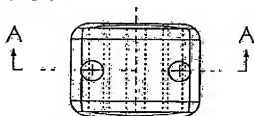


Fig. 20C

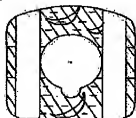


Fig. 20D

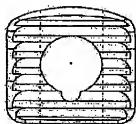


Fig. 20E

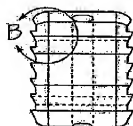


Fig. 20F

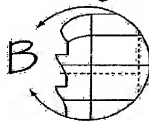


Fig. 20G





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Fig. 21A

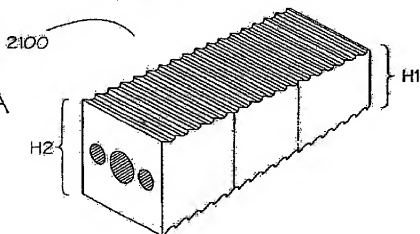


Fig. 21B

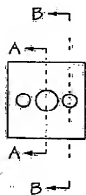


Fig. 21C

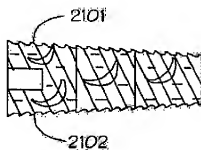


Fig. 21D



Fig. 21E



10/14

Fig. 22A

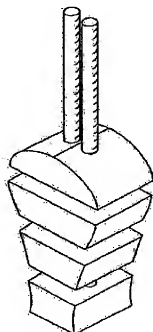
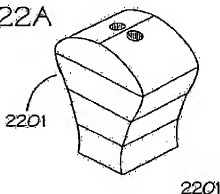


Fig. 22C

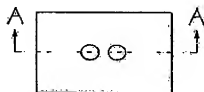


Fig. 22B

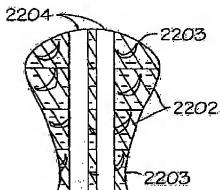


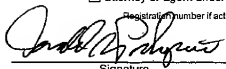
Fig. 22D



Fig. 22E



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<b>PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)</b> <b>FY 2005</b> <b>(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)</b>		Docket Number (Optional) 13990US92
Application Number 09/782,594		Filed February 12, 2001
For <b>ASSEMBLED IMPLANT</b>		
Art Unit 3738	Examiner Paul B. Preblich	
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):		
	<b>Fee</b>	<b>Small Entity Fee</b>
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60 \$
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225 \$
<input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020 <i>1st month paid</i>	\$510 <u>\$910</u>
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795 \$
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080 \$
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.		
<input checked="" type="checkbox"/> A check in the amount of the fee is enclosed. One-month-extension fee already paid.		
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.		
<input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.		
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>13-0017</u> . I have enclosed a duplicate copy of this sheet.		
<b>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</b>		
I am the <input type="checkbox"/> applicant/inventor.		
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71		
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/56).		
<input checked="" type="checkbox"/> attorney or agent of record. Registration Number <u>32,167</u>		
<input type="checkbox"/> attorney or agent under 37 CFR 1.34. <u>01/26/2005 BARBARA 00000105 09782594</u>		
Registration number if acting under 37 CFR 1.34. <u>02 FC:1253</u> <b>910.00 BP</b>		
 Signature		January 20, 2005
Donald J. Pochopien		Date
Typed or printed name		312-775-8000
		Telephone Number

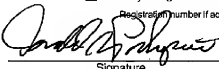
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.  
If you need assistance in completing this form, call 1-800-PTO-9199 and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)</b> <b>FY 2005</b> <b>(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4816).)</b>		Docket Number (Optional) 13980US92
Application Number 09/782,594		Filed February 12, 2001
For <b>ASSEMBLED IMPLANT</b>		
Art Unit 3738		Examiner Paul B. Preblich
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.		
The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):		
	Fee	Small Entity Fee
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60 \$
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225 \$
<input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020 <i>1st month paid</i>	\$510 <u>\$910</u>
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795 \$
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080 \$
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.		
<input checked="" type="checkbox"/> A check in the amount of the fee is enclosed. One-month extension fee already paid.		
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.		
<input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.		
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>13-0017</u> . I have enclosed a duplicate copy of this sheet.		
<b>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</b>		
I am the <input type="checkbox"/> applicant/inventor.		
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71		
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).		
<input checked="" type="checkbox"/> attorney or agent of record. Registration Number <u>32,167</u>		
<input type="checkbox"/> attorney or agent under 37 CFR 1.34. <u>01/26/2005 BARRAHAI 00000105 09782594</u>		
Registration number if acting under 37 CFR 1.34. <u>02 FC:1253</u> <b>910.00 BP</b>		
 Signature		January 20, 2005
Donald J. Pochochian		Date
Typed or printed name		312-775-8000
		Telephone Number
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.		
<input type="checkbox"/> Total of _____ forms are submitted.		

This collection of information is required by 37 CFR 1.136(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

## **EXHIBIT 16**



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1456  
Alexandria, Virginia 22313-1456  
www.uspto.gov

12

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490

7590 03/24/2005  
DONALD J. POCHOPIEN  
McANDREWS, HELD & MALLOY, LTD.  
CITICORP CENTER, 34TH FLOOR  
500 WEST MADISON STREET  
CHICAGO, IL 60661

EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/782,594

Examiner

Paul B. Preblich

Applicant(s)

BIANCHI ET AL.

Art Unit

3738

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/1/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### ***Drawings***

A proposed drawing corrections filed January 24, 2005 have been approved for entry.

Upon review of present claims over the subject matter of the various parent applications and related applications, it was determined that claims 26-33 have an effective filing date of February 12, 2001. In particular, claims 26-31 and 33-34 have this date because of the "one or more . . pins", "two or more" or "three" connected bone portions in combination with bone pins; there are only 2 bone portions and 4 pins set forth as the sole example in the parent application (see Figure 7 and page 17 of 08/920,630). Furthermore, claims 30 and 32 have this date because of the "cancellous" bone portions where the implant constitutes two or more portions that have been connected together by press fitting.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 79 of copending Application No. 09/941,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claim 79 is read on by what is set forth in the claims of this application such claim 79 would be anticipated thereby. For this reason, the claims are considered obvious in view of claim 79; see *In re Goodman, supra*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Claim Objections***

Claim 29 is objected to because of the following informalities:

On line 2 of claim 29, the use of "comprising" is confusing because the bone graft has several other elements already set forth in the base claim. For this reason, the Examiner suggests replacing "comprising" with ---where there are--- in order to overcome this objection. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. On line 4 of claim 27, "said composite bone graft" lacks antecedent basis, and thus, the claim scope is considered to be indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (US 6,200,347). Anderson anticipates the claim language where the bone portions as claimed are the bone grafts (16 and 17 of Figure 7 or elements 2 and 4 of Figure 1) and the pins of Anderson are threaded and do not contain adhesive (see column 5; lines 29-33); see also column 19, line 62 to column 20, line 36 and column 5, lines 1-8. The interference fit of Anderson with a smaller hole than the pin is considered to be the same as a press fit; see column 5, lines 29-33.

Claims 26-28, 30, 31, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis (US 5,147,367). Ellis anticipates the claim language where the bone pieces or bone portions of the same patient are grafted back onto the bones they were separated from to form a graft; see the figures, the abstract and column 5, lines 12-56. "Graft" is denoted as "anything inserted into something else so as to become an integral part of the latter"; Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, p. 599. For this reason

the separated bone piece(s) are grafts when this term is given its broadest reasonable interpretation.

With regard to claim 27, the breaks or separations are in cortical bone because cortical bone is on the outside of bone and it is visible in the drawings.

With regard to claim 28, the pins of Ellis are cortical bone pins because they are for cortical bone the same way a "bone screw" is for bone but can be made of a metal.

Claims 26, 27, 31, and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ochoa (US 5,716,358). Ochoa meets the claim language where the bone pieces or bone portions of the same patient are grafted back onto the bones they were separated from to form a graft; see the Figures 4 and 5 as well as column 6, line 57 to column 8, line 47. "Graft" is denoted as "anything inserted into something else so as to become an integral part of the latter"; Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, p. 599.

Claims 26-31 and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Yaccarino, III (US 6,025,538). Yaccarino anticipates the claim language where two or more bone portions are joined with two bone pins; see Figures 8 to 15 and column 5, line 55 to column 7, line 14.

With regard to claim 29, Applicants are directed to column 9, lines 55-67.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yaccarino, III (US 6,025,538) alone. Yaccarino meets the claim language as set forth in the previous rejection, but fails to teach a cancellous bone portion press-fitted in the hole as claimed. However, Yaccarino prefers cortical bone for his press-fitted pins and states that allograft bone contains both cortical and cancellous bone; see column 1, lines 31-45. Yaccarino adds that allograft is used to make bone pins. Therefore, it is the Examiner's position that it would have been considered prima facie obvious to make the pins of Yaccarino with some cancellous bone in order to better encourage bone ingrowth throughout the implant.

#### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but were not considered persuasive.

In response to the argument that all the claims have an effective filing date of August 23, 1997, the Examiner does not agree and has altered the explanation above to point out where the support is lacking. In particular, claims 26-31 and 33-34 have the effective filing date of February 12, 2001 because the subject matter of "one or more . . . pins", "two or more" or "three" connected bone portions in combination with bone pins was not disclosed in 08/920,630; there are only 2 bone portions and 4 pins set forth as the sole example (see Figure 7 and page 17 of 08/920,630). Furthermore, claims 30 and 32 have this date because of the "cancellous" bone portions where the implant

constitutes two or more portions that have been connected together by press fitting was not disclosed in the parent application.

The remaining argument of the November 22, 2004 response were rendered moot in view of the new grounds of rejection set forth.

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

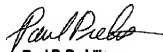
Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebille whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Paul B. Prebille  
Primary Examiner



# **Notice of References Cited**

Application/Control No.

09/782,594

Applicant(s)/Patent Under

Reexamination  
BIANCHI ET AL.

Examiner

Paul B. Prebille

Art Unit

3738

Page 1 of 1

## **U.S. PATENT DOCUMENTS**

* A	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
A	US-4,969,909	11-1990	Barouk, Louis S.	623/21.15
B	US-5,571,190	11-1995	Ulrich et al.	623/17.11
C	US-5,112,354	05-1992	Sires, Bryan S.	600/36
D	US-5,147,367	09-1992	Ellis, Alfred B.	605/96
E	US-5,180,388	01-1993	DiCarlo, Paul	605/60
F	US-5,716,358	02-1998	Ochoa et al.	605/62
G	US-5,865,848	02-1999	Baker, Gregg S.	623/17.15
H	US-2001/0039458	11-2001	Boyer et al.	623/23.63
I	US-			
J	US-			
K	US-			
L	US-			
M	US-			

## **FOREIGN PATENT DOCUMENTS**

* N	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
N					
O					
P					
Q					
R					
S					
T					

## **NON-PATENT DOCUMENTS**

* U	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	
V	
W	
X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

## **EXHIBIT 17**



ATTORNEY DOCKET NO. RTI 112R /1915-13980US02

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:

Bianchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

Group Art Unit: 3738

Examiner: Paul B. Prebilic

CERTIFICATE OF MAILING

I hereby certify that this document and all documents referred to herein are being sent by first class mail, postage prepaid, to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

July 15, 2005

Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.111

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of 03/24/05 (hereinafter "the Official Action"), for which a response was due 06/24/05, now extended one month to 07/24/05, the Applicants respond as follows:

Amendments to the Claims:

Pages 2-4

Remarks:

Pages 5-16

## Amendments to the Claims:

Please substitute the listing of the claims as provided below for any prior listings:

### Claims 1-25 (Cancelled)

26. (currently amended) An assembled bone graft, comprising: a plurality of bone portions layered to form a graft unit, and ~~one or more~~ biocompatible pins traversing said graft unit for holding said graft unit together, said assembled bone graft does not comprise an adhesive.

27. (currently amended) An assembled bone graft comprising:  
two distinct bone portions of cortical bone, and ~~one or more~~ biocompatible pins, wherein said biocompatible pins are of appropriate diameter and press fitted into machined holes in said two bone portions to hold together said two bone portions to form said ~~composite~~ assembled bone graft.

28. (currently amended) An assembled bone graft comprising two or more connected, distinct, bone portions forming a graft unit, and ~~two or more~~ cortical bone pins, said two or more connected, distinct, bone portions having holes therein for receiving said ~~two or more~~ cortical bone pins, said cortical bone pins keeping said two or more connected, distinct, bone portions aligned and connected, without an adhesive.

29. (currently amended) The assembled bone graft of claim 28 where there are comprising three ~~two~~ connected, distinct, bone portions.

30. (previously presented) The assembled bone graft of claim 28, wherein said two or more connected, distinct, bone portions are selected from the group consisting of: cortical bone and cancellous bone.

31. (currently amended) An assembled bone graft, comprising:  
a first bone portion having ~~one or more~~ holes therein;  
a second bone portion having ~~one or more~~ holes therein aligned with the holes in said first bone portion; and

~~one or more~~ cortical bone pins press-fitted in said holes for holding said first bone portion in juxtaposition to said second bone portion and forming a graft unit.

32. (currently amended) An assembled bone graft, comprising:  
a first cortical bone portion having a hole therein;  
a second cortical bone portion having a hole therein, said hole in said second cortical bone portion aligning with said hole in said first cortical bone portion;  
~~a cancellous bone portion~~ cortical bone pin press-fitted in the hole between said first cortical bone portion and said second cortical bone portion to form said assembled bone graft.

33. (currently amended) An assembled bone graft, comprising:  
a first cortical bone portion having ~~one or more~~ holes therein;  
a second cortical bone portion having ~~one or more~~ holes therein aligned with the holes in said first bone portion; and  
~~one or more~~ cortical bone pins press-fitted in said holes for holding said first cortical bone portion in stacked juxtaposition to said second cortical bone portion and forming a graft unit without an adhesive.

34. (currently amended) An assembled bone graft, comprising:  
a first bone portion;  
a second bone portion provided on said first bone portion to form a graft unit; and  
~~one or more~~ biocompatible pins inserted into said first bone portion and said second bone portion for holding together said graft unit.

35-60. (cancelled)

61. (New) The assembled implant of claim 31 wherein said cortical bone pins are four cortical bone pins.

62. (New) The assembled implant of claim 33 wherein said cortical bone pins are four cortical bone pins.

## REMARKS

The amendments to the claims do not add new matter. The amendments to the claims are consistent with the disclosure in the specification and in the priority application USSN 08/920,630, filed 08/27/97, now abandoned. The Applicants deleted the specific recitation of "one or more," "two or more" and "three or more" bone pins in favor of the more generic disclosures in USSN 08/920,630 of the plural term "bone pins" and the more specific disclosure of "4 bone pins." The Patent Office has already acknowledged support for "four" bone pins stating "there are only 2 bone portions and **4 pins** set forth as the sole example in the parent application." [Official Action at page 2, citing FIG. 7 and page 17.] Support for the undesignated plurality "bone pins" is found throughout the specification and is not so limited to "4" as shown in FIG. 7. See the specification of USSN 08/920,630 at page 5, lines 13-15 ("Such stacked implants may be maintained in a unitary association by drilling appropriate holes through the height of the implant, and inserting therein **appropriate retention pins** made from any desirable material, including **cortical bone**. . ."); and at page 17, lines 10-12 ("**Pins**, composed of **cortical bone**, resorbable but strong biocompatible synthetic material, or metallic **pins** of the appropriate diameter are then impelled into the **holes** in the implants such that the implants are formed into a unitary body by these **pins**"); and at page 17, lines 25-28 ("The two halves may be implanted in juxtaposition, or **holes** may be formed in each half, and the halves maintained in contact by forcing **pins** through the holes, in a fashion analogous to that described above for maintaining **stacked** implants in contact with each other"); emphasis added in bold. Thus, the earliest claimed priority application, parent application, USSN 08/920,630, filed 08/27/97, has written description support for a **genus** of implants having a plurality of "holes" and "pins", a **subgenus** of FIG. 8 (side by side) having "holes" and pins, a **subgenus** of stacked implants having "holes" and "pins", and a **species** of FIG. 7A-7B having "four" holes and "four" appropriately sized pins. These latter species are now claimed in new claims 61 and 62.

Claim 27, which has been amended to recite that the pins are of "appropriate diameter," is supported throughout the specification, including at page 17, lines 10-12 ("**Pins**, composed of cortical bone, resorbable but strong biocompatible

synthetic material, or metallic pins of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins.”).

Claim 33, which has been amended to recite that the implants are “stacked,” is supported throughout the specification, including at page 5, lines 13-15 (“Such **stacked** implants may be maintained in a unitary association by drilling appropriate holes through the height of the implant, and inserting therein **appropriate retention pins** made from any desirable material, including **cortical bone**. . . .”)

For all these reasons, the amendments to the claims do not add new matter.

### **Summary of the Bases for Objection /Rejection**

The Patent Office has assigned an effective filing date of 02/12/01 to claims 26-34.

Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting-over claim 79 of copending sister application USSN 09/941,154.

Claim 29 is objected to as to its form.

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite.

Claims 26-31 and 33 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.).

Claims 26-28, 30, 31, 33 and 34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis).

Claims 26, 27, 31 and 33-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,716,358 (Ochoa).

Claims 26-31 and 33-34 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,025,538 (Yaccarino).

Claim 32 is rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,025,538 (Yaccarino) alone.

Each of these nine bases for objection and/or rejection are addressed in Sections I-IX, respectively, which follow.

## I. Effective Filing Date of Claims 26-34

### "one or more"

The Patent Office contends that claims 26-34 are only entitled to the filing date of the present application—February 12, 2001. [Official Action at page 2.] Specifically, the Patent Office contends that "claims 26-31 and 33-34 have this date because of the 'one or more . . . pins', 'two or more' or 'three' connected bone portions in combination with bone pins. . . ." [Official Action at page 2.] According to the Patent Office, "there are only 2 bone portions and 4 **pins** set forth as the sole example in the parent application." [Official Action at page 2, citing FIG. 7 and page 17.] The Applicants respectfully submit that the priority application (USSN 08/920,630, filed 08/27/97) teaches the referenced Example, shown in FIG. 7, having 2 bone portions and 4 pins. However, the priority application also contains a generic teaching in words which supports a plurality of bone portions, which form a unitary construct using the plural designation of "**pins**" that are inserted in the corresponding plural designation "**holes**" insofar as these generic terms ("pins" and "holes") do not have the exact words "two or more" or "three or more" in front of them, the Applicants have amended the claims 26, 28, 31, 33 and 34, deleting the subgenus "one or more" and leaving the genus "pins."

Support for the generic term "bone pins" is found throughout the specification of the priority application (USSN 08/920,630 ) and is not so limited to "4" as shown in the species of FIG. 7. See the specification of USSN 08/920,630 at page 5, lines 13-15 ("Such stacked implants may be maintained in a unitary association by drilling appropriate **holes** through the height of the implant, and inserting therein **appropriate retention pins** made from any desirable material, including **cortical bone**. . . "); and at page 17, lines 10-12 ("**Pins**, composed of **cortical bone**, resorbable but strong biocompatible synthetic material, or metallic **pins** of the **appropriate diameter** are then impelled into the **holes** in the implants such that the **implants** [i.e., bone portions] are formed into a unitary body by these **pins**"; and at page 17, lines 25-28 relative to FIG. 8 ("The two halves may be implanted in juxtaposition, or **holes** may be formed in each half, and the halves maintained in contact by forcing **pins** through the holes, in a fashion analogous to that described above for maintaining **stacked implants** in contact with each other"); emphasis added in bold.

Thus, the earliest claimed-priority application, parent application, USSN 08/920,630, filed 08/27/97, has written description support for the following: i) a **genus** of implants having a plurality of "holes" and "pins"; ii) a **subgenus** of FIG. 8 (side by side) having "holes" and pins; iii) a **subgenus** of stacked implants having "holes" and "pins"; and iv) a **species** of FIG. 7A-7B having two bone portions with "four" holes (each) and "four" appropriately sized pins. These latter species are now claimed in new claims 61 and 62.

For all these reasons, the claims 26-34 have written description support in claimed priority application USSN 08/920,630, filed 08/27/97 and are entitled to the claimed priority date of 08/27/97.

#### **"cancellous bone portion"**

The Patent Office also contends that claims 30 and 32 are only entitled to the present filing date (02/12/01) because "of the '**cancellous**' bone portions where the implant constitutes two or more portions that have been connected together by press fitting." [Official Action at page 2; emphasis added in bold.] The Applicants have amended claim 32, which originally recited that a "cancellous" bone portion was press fitted into a hole. As amended, claim 32 now recites that a "cortical bone pin" is press fitted in the hole. Accordingly, claim 32 has written support in priority application USSN 08/920,630, filed 08/27/97.

Separately, claim 30 recites as follows:

The assembled bone graft of claim 28, wherein said two or more connected, distinct, bone portions are selected from the group consisting of: **cortical bone and cancellous bone**.

The Applicants respectfully submit that the specification of priority application USSN 08/920,630, filed 08/27/97, discloses making a shaped implant of "cancellous" bone:

In figure 3B, there is provided an end-on view of the **cancellous bone plug 310** after the broaching procedure is completed. As can be seen, the internal canal 104 has been converted from a circular canal into a substantially "D"-shaped canal. As will be appreciated from this disclosure, any of a number of different asymmetric shapes in the internal canal 104 may be defined by this or analogous means, the principal goal being to provide a purchase

(referred to herein as a "key-way") **within the implant** for external machining of the implant.

[USSN 08/920,630 at page 11, lines 7-13; emphasis added in bold.]

Thus, the priority application discloses the making and shaping of a "cancellous" "implant." Elsewhere, the priority application discloses the "stacking" of the previously disclosed "implants" (e.g., which includes the already disclosed cancellous implant):

In figure 7, there is shown a further aspect of this invention in which an **implant, either machined as described above**, or prior to said machining, is **further machined so as to allow stacking** thereof to achieve implants of various heights.

[USSN 08/920,630 at page 16, line 1 to page 17, line 2; emphasis added in bold.]

Thus, the priority application discloses the stacking of a plural number of "implants."

Finally, the specification discloses that these (plural) stacked "**implants**" are held together with pins, such as cortical bone pins:

... alternate methods of producing the implant of desired heights disclosed herein may be employed. For **example**, in a first such alternate method, **implants of this invention** are produced and then **stacked** to provide a **unitary implant** of the desired height dimensions. Such **stacked implants** may be maintained in a unitary association by drilling appropriate **holes** through the height of the implant, and inserting therein appropriate **retention pins** made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium or other metallic retention pins.

[[USSN 08/920,630 at page 5, lines 10-16; emphasis added in bold.]

Thus, priority application USSN 08/920,630, filed 08/27/97, discloses making a "unitary implant" from the shaped implants already disclosed which included an implant of figure 3 that was made from "cancellous" bone.

**"press fitting"**

In construing the "press-fit" limitation, the Patent Office stated that an "interference fit" and a **"snug fit"** (of the cited prior art) "is considered to be the same as a press fit." [Official Action of 01/04/05 at page 3.] In response, the Applicants wish to point out that the present invention claims priority to USSN 08/920,630, filed 08/27/97, now abandoned. A copy of this specification is attached as Exhibit A of the Applicants' Response to the Official Action of 11/04/03. This claimed priority application discloses the subject matter of claims 27 and 31-33, directed to an assembled implant comprising two cortical bone pieces that are held together by cortical bone pins that are press fitted into machined holes in the two cortical bone pieces:

**Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins.**

[USSN 08/920,630 at page 17, lines 10-12; emphasis added in bold.]

\* \* \*

In a further embodiment of this invention, shown in figure 8, a method for assembling the implant of this invention from component parts is provided. In figure 8A, there is shown an implant 800 composed of **two side-by-side halves, 801A and 801B.** The two halves of the implant are brought into juxtaposition to form a unitary implant. The two halves may be implanted in juxtaposition, or holes may be formed in each half, and the halves **maintained in contact by forcing pins through the holes, in a fashion analogous to that described above for maintaining stacked implants in contact with each other.**

[USSN 08/920,630 at page 17, lines 22-28; emphasis added in bold.]

Thus, the specification of Applicants' claimed priority application does disclose "forcing" or "impelling" pins, i.e., press-fitting pins, into the holes in the two portions of the implant.

For all these reasons, claims 26-34 are entitled to the priority filing date of 08/27/97.

## **II. Obviousness Type Double Patenting**

Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154. However, no claims have been allowed in either application, and may be subject to amendment. Applicants will reconsider the issue at such time as it is ripe and claims become allowed in either application.

## **III. Objection as to Form**

Claim 29 is objected to as to its form. In particular, the Patent Office has suggested that the use of "comprising" is confusing, and suggested instead the use of "where there are." [Official Action at page 3.] In response, the Applicants have amended claim 29 consistent with the Patent Office's suggestion. Accordingly, this basis for objection has been rendered moot.

## **IV. 35 U.S.C. § 112, Second Paragraph (Indefiniteness)**

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. According to the Patent Office, the use of "said composite" in claim 27 lacks antecedent basis. In response, the Applicants have amended claim 27 by deleting the phrase "said composite" and replacing it with "said assembled" bone graft for which there is antecedent support. Accordingly, this basis for rejection of claim 27 has been rendered moot.

## **V. 35 U.S.C. § 102(e) over U.S. Pat. 6,200,347 (Anderson)**

Claims 26-31 and 33 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.). Anderson has an earliest claimed priority filing date of 01/05/99. Applicants have again amended claims 26-34 in conformity with the Applicants priority application USSN 08/920,630, filed 08/27/97. Moreover, in Section I herein, the Applicants have cited to those portions of Applicants' claimed priority application USSN 08/920,630, filed 08/27/97, that support claims 26-31 and 33.

Accordingly, Anderson, which has an earliest claimed priority date of 01/05/99, is not prior art against the present claimed invention .

**VI. 35 U.S.C. § 102(b) over U.S. Pat. 5,147,367 (Ellis)**

Claims 26-28, 30-31 and 33-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, "Ellis anticipates the claim language where the bone pieces or bone portions of the same patient are grafted back **onto the bones they were separated from** to form a graft. . . ." [Official Action at page 4, citing Ellis at the figures, the abstract, and column 5, lines 12-56; emphasis added in bold.] Thus, in the bolded language above, the Patent Office acknowledges that Ellis discloses binding the bone back to its **original** location (*i.e.*, the location that it was "**separated from**"). As support for its position, the Patent Office cites to Stedman's Medical Dictionary, 23<sup>rd</sup> Edition at page 599 for the definition of "graft" as "anything inserted into something else so-as to become an integral part of the latter." [Official Action at page 4.] However, the definition upon which the Patent Office relies misses the fine part of the definition which requires that the "anything" come from a "**different site or source**." As support for the Applicants' position, the Applicants cite to the following three medical dictionaries, including Stedman's, as relied upon by the Patent Office, which did include the definition of "bone graft" as specifically recited in Applicants' claims:

**graft** - a tissue or an organ taken from a site or a person and inserted into a **new site or person**, performed to repair a defect in structure.

[Exhibit A: Mosbey's Medical, Nursing and Allied Health Dictionary, The C.V. Mosbey Co., St Louis, 1990, Eds. Glanze, et al., at page 531 ; emphasis added in bold.]

\* \* \*

**grafting** - The implantation of skin or other tissue, **from a different site or source**, to replace damaged tissue.

[Exhibit B: Dorland's Illustrated Medical Dictionary, W.B. Saunders & Co., 24<sup>th</sup> Edition, Philadelphia, 1965, at page 629; emphasis added in bold.]

**bone graft** - bone transplanted from a **donor site** to a **recipient site**.

[Exhibit C: Stedman's Medical Dictionary, 24<sup>th</sup> Edition, Williams & Wilkins, Baltimore, 1982, at page 604, emphasis added in bold.]

Thus, the art as a whole, including the dictionary relied upon by the Patent Office, recognizes that a "graft" is tissue that comes from a **"different site or source."** Accordingly, when Ellis discloses binding a fracture piece of bone back to its original location, it is not a "graft" because the broken piece of bone is not from a **"different site or source"** or from a **"donor site,"** nor is it moving to a **"new site."** For all these reasons, claims 26-28, 30-31 and 33-34 are not anticipated by U.S. Pat. 5,147,367 (Ellis) under 35 U.S.C. § 102(b).

#### **VII. 35 U.S.C. § 102(b) over U.S. Pat. 5,716,358 (Ochoa)**

Claims 26, 27, 31 and 33-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,716,358 (Ochoa). According to the Patent Office, "Ochoa meets the claim language where the bone pieces or bone portions of the same patient are grafted back **onto the bones they were separated from** to form a graft. . . ." [Official Action at page 5, citing Ochoa at Figures 4 and 5, and column 6, line 57 to col. 8, line 47; emphasis added in bold.] In the bolded language above, the Patent Office acknowledges that Ochoa discloses binding the bone back to its **original** location (i.e., the location that it was **"separated from"**). As support for its position, the Patent Office cites to Stedman's Medical Dictionary, 23<sup>rd</sup> Edition at page 599 for the definition of "graft" as "anything inserted into something else so as to become an integral part of the latter." [Official Action at page 5.] However, the definition upon which the Patent Office relies misses the fine part of the definition of "graft" which requires that the "anything" come from a **"different site or source."** As support for the Applicants' position, the Applicants cite to the following three medical dictionaries, including Stedman's, as relied upon by the Patent Office, which did include the definition of "bone graft" as specifically recited in Applicants' claims:

**graft** - a tissue or an organ taken from a site or a person and inserted into a **new site or person**, performed to repair a defect in structure.

[Exhibit A: Mosbey's Medical, Nursing and Allied Health Dictionary, The C.V. Mosbey Co., St Louis, 1990, Eds. Glanze, et al., at page 531; emphasis added in bold.]

\* \* \*

**grafting** - The implantation of skin or other tissue, **from a different site or source**, to replace damaged tissue.

[Exhibit B: Dorland's Illustrated Medical Dictionary, W.B. Saunders & Co., 24th Edition, Philadelphia, 1965, at page 629; emphasis added in bold.]

\* \* \*

**bone graft** - bone transplanted from a **donor site** to a **recipient site**.

[Exhibit C: Stedman's Medical Dictionary, 24<sup>th</sup> Edition, Williams & Wilkins, Baltimore, 1982, at page 604, emphasis added in bold.]

Thus, the art as a whole, including the dictionary relied upon by the Patent Office, recognizes that a "graft" is tissue that comes from a **"different site or source."** Accordingly, when Ochoa discloses binding a fractured piece of bone back to its **original** location, it is not a "graft" because the broken piece of bone is not from a **"different site or source"** or from a **"donor site,"** nor is it moving to a **"new site."** For all these reasons, claims 26, 27, 31 and 33-34 are not anticipated by U.S. Pat. 5,147,367 (Ellis) under 35 U.S.C. § 102(b).

#### VIII. 35 U.S.C. § 102(c) over U.S. Pat. 6,025,538 (Yaccarino)

Claims 26-31, and 33-34 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,025,538 (Yaccarino). Yaccarino has an earliest claimed priority filing date of 01/20/98. Applicants have again amended claims 26-34 in conformity with the Applicants priority application USSN 08/920,630, filed 08/27/97. Moreover, in Section I herein, the Applicants have cited to those portions of Applicants' claimed priority application USSN 08/920,630, filed 08/27/97, that support claims 26-31 and 33-34. Accordingly, Yaccarino, which has an earliest claimed priority date of 11/20/98 is not prior art against the present claimed invention.

**IX. 35 U.S.C. § 103(a) over U.S. Pat. 6,025,538 (Yaccarino)**

Claim 32 is rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,025,538 (Yaccarino) alone. Yaccarino has an earliest claimed priority filing date of 01/20/98. The Applicants have amended claim 32, which originally recited that a "cancellous" bone portion was press fitted into a hole. As amended, claim 32 now recites that a "cortical bone pin" is press fitted in the hole. Support for "cortical bone pins" is found in Applicants' priority application USSN 08/920,630, filed 08/27/97, at page 17, lines 10-12 ("**Pins**, composed of **cortical bone**, resorbable but strong biocompatible synthetic material, or metallic **pins** of the **appropriate diameter** are then impelled into the **holes** in the implants such that the **implants** [i.e., bone portions] are formed into a unitary body by these **pins**"); and at page 17, lines 25-28 relative to FIG. 8 ("The two halves may be implanted in juxtaposition, or **holes** may be formed in each half, and the halves maintained in contact by forcing **pins** through the holes, in a fashion analogous to that described above for maintaining stacked implants in contact with each other"); emphasis added in bold. Accordingly, claim 32 has written support in priority application USSN 08/920,630, filed 08/27/97. Therefore, Yaccarino, which has an earliest claimed priority date of 11/20/98 is not prior art against the present claimed invention.

**CONCLUSION**

Claims 26-34 are pending and subject to rejection. Claims 61-62 have been added by amendment herein.

The Applicants have shown that claims 26-34 have an effective filing date of 08/27/97. The rejection of claims 26-34 under 35 U.S.C. § 102(c) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.) or U.S. Pat. 6,025,538 (Yaccarino) have been rebutted. The rejection of claims 26-28, 30-31, and 33-34 under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis) have been rebutted. The rejection of claims 26, 27, 31 and 33-34 under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,716,358 (Ochoa) have been rebutted. The rejection of claim 32 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,025,538 (Yaccarino) alone has been

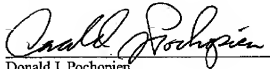
rendered moot by the amendment herein. Finally, the above-recited bases for rejection should not be applied to newly submitted claims 61 and 62 for the reasons already provided herein.

Claims 26-34 and 61-62 are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:



Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8133

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to study the personnel issues in medicine. The Committee issued its final report in September 1980. Among its conclusions were those regarding the supply of nurses in expanded roles, including nurse practitioners and nurse midwives.

**Graduate Record Examination (GRE)**, an examination administered to graduates of institutions of higher learning. The scores are used as criteria for admission to masters and doctoral programs in many institutions and areas of specialization, including nursing. The examination tests verbal and mathematical aptitudes and abilities.

**GRAE**, abbreviation for generally recognized as effective.

**graft** [*Gk graphion stylus*], a tissue or an organ taken from a site or a person and inserted into a new site or person, performed to repair a defect in structure. The graft may be temporary, such as an emergency skin transplant for extensive burns, or permanent, such as the grafted tissue growing to become a part of the body. Skin, bone, cartilage, blood vessel, nerve, muscle, cornea, and whole organs, such as the kidney or the heart, may be grafted. Preoperative care focuses on a high protein diet and vitamins to ensure optimum physical condition and on freedom from infection. Under general or local anesthesia the tissue is transferred and sutured into place. Rejection is the major complication: fever, pain in the graft area, and evidence of loss of function 4 to 15 days after the procedure are indicative of rejection. Immunosuppressive drugs are given in large doses to suppress antibody production and rejection. Even if an early reaction is blocked, late rejection may occur 1 year or more after the graft is done. Also called **transplant**. See also **allograft**, **autograft**, **isograft**, **skin graft**, **xenograft**.

**graft-versus-host reaction**, a rejection response of certain grafts, especially bone marrow. It involves an incompatibility resulting from a deficiency in the immune response of some patients and is commonly associated with inadequate immunosuppressive therapy. Characteristic signs may include skin lesions with edema, erythema, ulceration, scaling, and loss of hair. Such reactions may also cause lesions of the joints and the heart and hemolytic anemia with a positive Coombs' reaction. The **graft-versus-host reaction** is similar to the Type IV reaction in hypersensitive individuals who receive tuberculin injections. Some experts believe that it involves certain immunologically active cells that originate as the result of defective tolerance mechanisms or as the result of somatic mutation of certain host cells. Also called **homologous disease**.

**Graham's law**, the law stating that the rate of diffusion of a gas through a liquid (or the alveolar-capillary membrane) is directly proportional to its solubility coefficient and inversely proportional to the square root of its density.

**grain** (*gr*) [*L granum seed*], the smallest unit of mass in avoirdupois, troy, and apothecaries' weights, being the same in all and equal to 4.79891 mg. The troy and apothecaries' ounces contain 480 grains; the avoirdupois ounce contains 437.5 grains.

**grain itch**, a skin condition caused by a mite that lives in grain or straw. The lesion consists of an intensely itchy, urticarial papule surmounted by a tiny vesicle.

**gram** (*g, gm*) [*L gramma small weight*], a unit of mass in the metric system equal to  $\frac{1}{1000}$  of a kilogram, 15.432

grains, and 0.0353 ounce avoirdupois. The preferred abbreviation is *g*.

**-gram, -gramme**, 1. a combining form meaning a 'drawing': *cephalogram, mammogram, splenogram*. 2. a combining form meaning '1/1000 kilogram': *centigram, decagram, microgram*.

**gram calorie**. See **calorie**.

**gram-equivalent weight (gEq)**, an equivalent weight of a substance calculated as the gram mass that contains, replaces, or reacts with (directly or indirectly) the Avogadro number of hydrogen atoms. As 1 atom of sulfur (atomic weight 32) combines with 2 atoms of hydrogen (atomic weight 1), the gram equivalent weight of sulfur is  $32/2 = 16$ .

**gram-molecular weight (gmW)**, an amount in grams equal to the molecular weight of a substance, or the sum of all the atomic weights in its molecular formula. In the example of carbon dioxide ( $\text{CO}_2$ ), its gram molecular weight is 12 (atomic weight of carbon) +  $2 \times 16$  (atomic weight of oxygen), or 44 *g*. See also **mole**, **molecular weight**.

**gram-negative** [*Hans C. J. Gram, Danish physician, b. 1853; L negare to say no*], having the pink color of the counterstain used in Gram's method of staining microorganisms. This property is a primary method of characterizing organisms in microbiology. Some of the most common gram-negative pathogenic bacteria are *Bacteroides fragilis*, *Brucella abortus*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Neisseria gonorrhoeae*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Salmonella typhi*, *Shigella dysenteriae*, and *Yersinia pestis*.

**gram-positive** [*Hans C. J. Gram; L positivus*], retaining the violet color of the stain used in Gram's method of staining microorganisms. This property is a primary method of characterizing organisms in microbiology. Some of the most common kinds of gram-positive pathogenic bacteria are *Bacillus anthracis*, *Clostridium*, *Mycobacterium leprae*, *Mycobacterium tuberculosis*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*.

**Gram's stain** [*Hans C. J. Gram*], the method of staining microorganisms using a violet stain, followed by an iodine solution, decolorizing with an alcohol or acetone solution, and counterstaining with safranin. The retention of either the violet color of the stain or the pink color of the counterstain serves as a primary means of identifying and classifying bacteria. Also called **Gram's method**. See also **gram-negative**, **gram-positive**.

**grand mal seizure** [*Fr, great; illness; saisir to seize*], an epileptic seizure characterized by a generalized involuntary muscular contraction and cessation of respiration followed by tonic and clonic spasms of the muscles. Breathing resumes with noisy respirations. The teeth may be clenched, the tongue bitten, and control of the bladder lost. As this phase of the seizure passes, the person may fall into a deep sleep for 1 hour or more. Usually, the person has no recall of the seizure or awakening. A sensory warning, or aura, usually precedes each grand mal seizure. These seizures may occur singly, at intervals, or in close succession. Anticonvulsant medications are usually prescribed as prophylaxis against grand mal seizures. Compare **focal seizure**, **petit mal seizure**, **psychomotor seizure**.

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yonic chick  
and subcu-  
l instead of  
Davis g.,  
lap of skin  
and subse-  
posed of  
le-mend g.,  
1's g., sieve  
fermic g.,  
raw surface.  
d by spread-  
eration and  
a prepared

pocket. **fascia g.**, a graft taken from the fascia lata or from the lumbar fascia. **fascicular g.**, a nerve graft in which the bundles of nerve fibers are approximated and sutured separately. **fat g.**, a graft of fat freed from its bed; used in filling depressions. **free g.**, a graft of tissue completely freed from its bed. **full-thickness g.**, a skin graft consisting of the full thickness of the skin, with none of the subcutaneous tissue. **gauntlet g.**, pedicle g., **Gillies' g.**, rope g., **heterodermic g.**, a skin graft taken from the body of a person other than the patient. **heterologous g.**, heterograft. **homologous g.**, homograft. **hyperplastic g.**, a skin graft which is in a state of active repair, as in recovery from inflammation. **implantation g.**, a graft in which small pieces of skin are embedded in granulation tissue. **island g.**, a flap of skin and subcutaneous tissue with a pedicle containing the nutrient vessels. **isologous g.**, isograft. **jump g.**, a pedicle graft transferred from one location to another in successive stages. **Krause-Wolfe g.**, a graft of full thickness of the skin. **lamellar g.**, replacement of the superficial layer of an opaque cornea by a thin layer of clear cornea from a donor eye. **Ollier-Thiersch g.**, a very thin graft including the epidermis and nearly always some of the derma. **omental g.'s**, strips of omentum to cover the line of esophagectomy. **osseous g.**, bone g., **pedicle g.**, a graft consisting of the full thickness of the skin and the subcutaneous tissue attached by a pedicle. **penetrating g.**, a full-thickness corneal transplant. **perforated g.**, a piece of peritoneum applied to a debrided area of a bone. **pinch g.**, a piece of skin about 1 in. in diameter, obtained by elevating the skin with a needle and slicing it off with a knife. The thickness of the graft may vary, but it is always free of fat. **Reverdin g.**, epidermic g., **rope g.**, a graft made by elevating a long strip of tissue from its bed except at the two extremities, the cut edges then being sutured together to form a tube. **seed g.**, implantation g., **sieve g.**, a graft in which the portion of skin to be removed has had circular islands cut out of it, these islands being left on the donor area. **skin g.**, a bit of skin implanted to replace a lost part of the integument. **sleeve g.**, a graft for repairing traumatic gaps in nerves by a sleeve-like extension from the distal stump which is sutured to the central stump. **split-skin g.**, a skin graft consisting of only half the skin thickness. **Stent g.**, Esser g., **thick-split g.**, a skin graft cut in large pieces, often including about two thirds of the full thickness of the skin. **Thiersch's g.**, Ollier-Thiersch g., **thyroid g.**, a piece of the thyroid body implanted in the tissues as a remedy for myxedema. **tube g.**, **tunnel g.**, rope g., **white g.**, **Wolfe g.**, **Wolfe-Krause g.**, **Krause-Wolfe g.**, **zoo-plastic g.**, animal g.

**grafting (graf'ting)**. The implantation of skin or other tissue, from a different site or source, to replace damaged structures.

**Graham's law (gr'a'mz)** [Thomas Graham, English chemist, 1805-1869]. See under law.

**Graham's test (gr'a'mz)** [Everts Ambrose Graham, American surgeon, 1883-1957]. See under test.

**Graham Steell murmur (gr'a'mz stel)** [Graham Steell, English physician, 1851-1942]. See under murmur.

**Grahamella (gr'a'm-el'lah)**. A genus of the family Bartonellaceae, order Rickettsiales, made up of Bartonella-like microorganisms, and occurring as two species, *G. peruviana* and *G. talpae*, infecting deer and moles, respectively.

**grahamellosis (gr'a'm-el-o'sis)**. Infection with organisms of the genus *Grahamella*.

**grain (grān)** [L. *grānum*]. 1. A seed, especially of a cereal plant. 2. The twentieth part of a scruple: 0.055 gram. **cayenne pepper g.'s**, brown crystals of uric acid in the urine. **V-shaped g.'s**, a system of separate grains of colorable material

(each grain united with an achromatic thread) in the ovum.

**grainage (grān'ij)**. Weight in grains or parts of a grain.

**gram (gram)** [Fr. *gramme*]. The basic unit of mass (weight) of the metric system, being the equivalent of 15.432 grains. Abbreviated G. or Gm.

**-gram (gram')** [Gr. *gramma* that which is written; a mark]. Word termination meaning that which is written or recorded.

**Gram's method, stain, solution (gramz)** [Hans Christian Joachim Gram, Danish physician, 1853-1938]. See Table of Stains and Staining Methods, under stain, and also under solution.

**gramicidin (gram'ī-sī'din)**. An antibacterial substance produced by the growth of *Bacillus brevis*, one of the two principal components of tyrothricin. Called also *gramicidin D*.

**gramine (gram'in)**. A crystalline indole alkaloid,  $C_{12}H_{14}N_2$ , from barley.

**graminin (gram'tī-nin)**. A fructosan from rye flour.

**gram-ion (gram'ī-on)**. A quantity of an ion whose weight in grams is numerically equal to the atomic weight of the ion.

**gramme (gram)** [Fr. *Gram*].

**grammeter (gram'mē-ter)**. A unit of work, representing the energy expended in raising 1 Gm. of weight 1 meter vertically against gravitational force. It is one thousandth of a kilogrammeter, or about 98,000 ergs.

**grammole (gram'mol)**. Gram-molecule.

**gram-molecule (gram'mol'icūl)**. As many grams of a substance as are numerically equal to its molecular weight.

**gram-negative (gram-neg'ah-tiv)**. Losing the stain or decolorized by alcohol in Gram's method of staining, a primary characteristic of certain microorganisms (see Table).

**gram-positive (gram-poz'ah-tiv)**. Retaining the stain or resisting decolorization by alcohol in Gram's method of staining, a primary characteristic of certain microorganisms (see Table).

TABLE OF GRAM-NEGATIVE AND GRAM-POSITIVE BACTERIA  
(After Waksman and Schatz)

Gram-Negative	
<i>Aerobacter aerogenes</i>	<i>Neisseria intracellulæria</i>
<i>Brucella abortus</i>	<i>Pasteurella leptopneumoniae</i>
<i>Brucella melitensis</i>	<i>Pasteurella putris</i>
<i>Brucella suis</i>	<i>Pasteurella tularensis</i>
<i>Escherichia typhi</i>	<i>Proteus vulgaris</i>
<i>Escherichia coli</i>	<i>Pseudomonas aeruginosa</i>
<i>Escherichia communior</i>	<i>Salmonella antracis</i>
<i>Haemophilus influenzae</i>	<i>Salmonella enteritidis</i>
<i>Haemophilus pertussis</i>	<i>Salmonella schottmülleri</i>
<i>Klebsiella ozaenæ</i>	<i>Salmonella saintpauli</i>
<i>Klebsiella pneumoniae</i>	<i>Shigella dysenteriae</i>
<i>Malleomyces mallei</i>	<i>Vibrio comma</i>
<i>Neisseria gonorrhoeae</i>	
Gram-Positive	
<i>Actinomyces bovis</i>	<i>Erysipelothrix rhusiopathiae</i>
<i>Bacillus anthracis</i>	<i>Mycobacterium tuberculosis</i>
<i>Clostridium butyricum</i>	<i>Streptococcus aureus</i>
<i>Clostridium septicum</i>	<i>Streptococcus faecalis</i>
<i>Clostridium sorbellei</i>	<i>Strept. hemolyticus</i>
<i>Clostridium tetani</i>	<i>Strept. lactis</i>
<i>Clostridium welchii</i>	<i>Strept. salivarius</i>
<i>Corynebacterium diphtheriae</i>	<i>Strept. viridans</i>
<i>Diplococcus pneumoniae</i>	

**granatoin (gran-ah-to'in)**. Pseudopelletierin.

**granatum (grān-na'tum)**, gen. *grana'ti* [L.]. Pomegranate.

**Grancher's disease, system (grān-shān)** [Jacques Joseph Grancher, French physician, 1843-1907]. See under disease and system.

**grandiosity (grān'de-ōs'ī-tē)**. A condition characterized by delusions of grandeur.

**grand mal (grān mahl)**. See epilepsy.

**Grandry's corpuscles (grān-drēz)** [French anatomist of the 19th century]. See under corpuscle.

ILLUSTRATED  
**Stedman's**  
**MEDICAL**  
**DICTIONARY**  
**24TH EDITION**



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adipodermal g., dermal-fat g.  
 allogenic g., allograft.  
 anastomosed g., one in which circulation is established by surgical anastomoses of blood vessels.  
 animal g., zoograft.  
 augmentation g., a g. of material used to increase the size, shape, or volume of a structure.  
 autochthonous g., autograft.  
 autodermic g., a skin autograft.  
 autogenous g., autograft.  
 autologous g., autograft.  
 autoplasmic g., autograft.  
 Blair-Brown g., a split-skin g. of intermediate thickness.  
 bone g., bone transplanted from a donor site to a recipient site.  
 brephoplastic g., a g. from an embryo or newborn to an adult.  
 cable g., a multiple strand nerve g. arranged as a pathway for regeneration of axons.  
 chessboard g.'s, obsolete synonym for postage stamp g.'s.  
 chip g., a g. utilizing small pieces of cartilage or bone which is packed into a bone defect.  
 chorioallantoic g., transplanting of living material to the chorioallantoic membrane of the embryonic chick.  
 composite g., a g. composed of several structures, such as skin and cartilage or a full-thickness segment of the ear.  
 corneal g., keratoplasty.  
 cutis g., g. of corium, from which epidermis and subcutaneous tissue have been separated.  
 Davis g.'s, small pieces (2 to 3 mm) of full-thickness skin.  
 delayed g., application of a skin g. after waiting several days for healthy granulations to form.  
 dermal g., a g. of dermis, made from skin by cutting away a thin split-skin g.  
 dermal-fat g., adipodermal g.; a dermal g. with attached subcutaneous fat.  
 Douglas g., obsolete synonym for sieve g.  
 epidermic g., a g. supposed to contain only epidermis.  
 Esser g., inlay g.  
 fascia g., g. of fibrous tissue, usually the fascia lata.  
 fascicular g., a nerve g. in which each bundle of fibers is approximated and sutured separately.  
 fat g., a free g. of fat.  
 filler g., a g. used for the filling of defects, e.g., filling a cyst with bone chips.  
 free g., a g. transplanted without its normal attachments, or a pedicle, from one site to another.  
 full-thickness g., a g. of the full-thickness-of-skin and subcutaneous tissue.  
 funicular g., a nerve g. in which each funiculus (composed of two or more fasciculi) is approximated and sutured separately.  
 heterologous g., heterograft.  
 heteroplastic g., heterograft.  
 heterospecific g., heterograft.  
 heterotopic g., transplantation of a tissue or organ into a position it normally does not occupy.  
 homologous g., homograft.  
 homoplastic g., homograft.  
 hyperplastic g., a g. in active proliferation.  
 implantation g., placing of Davis g.'s deep into the interstices of granulation tissue.  
 infusion g., transplantation by injection of a suspension of cells.  
 inlay g., epithelial inlay; Esser g., or operation; a skin g. wrapped (raw side out) around a bolus of dental compound and inserted into a prepared surgical pocket.  
 interspecific g., heterograft.  
 isogenic g., isograft.  
 isologous g., isograft.  
 isoplastic g., isograft.  
 Krause g., a full-thickness skin g.  
 mesh g., accordion g.  
 mucosal g., a g. of mucous membrane, usually the full-thickness of the lining of the cheek or lower lip.  
 nerve g., a nerve, or part of a nerve, used as a g.  
 Ollier g., Ollier-Thiersch g.; Thiersch g.; a thin split-skin g., usually in small pieces.  
 omental g., a segment of omentum, with its supplying blood vessels, transplanted as a free flap to a distant area and revascularized by arterial and venous anastomoses.

onlay g., a bone g. applied on the outside of the recipient bone(s).  
 orthotopic g., transplantation of a tissue or organ into its normal anatomical position.  
 osteoperiosteal g., a g. of bone with its attached periosteum.  
 pedicle g., see pedicle flap.  
 periosteal g., a g. of periosteum, usually placed on bare bone.  
 pinch g., Reverdin g.; small bits of skin, partial- or full-thickness, removed from healthy area and seeded in site to be covered.  
 porcine g., a split-skin g. from a pig, applied to a raw area on a human as a temporary dressing.  
 postage stamp g.'s, small pieces cut from a sheet of split-skin g.  
 primary skin g., a skin g. transferred immediately after the creation of a raw area.  
 punch g.'s, small g.'s of the full-thickness of the scalp, removed with a circular punch and transplanted to a bald area to grow hair.  
 Reverdin g., pinch g.  
 sieve g., a full-thickness skin g. taken after cutting multiple holes in it with a circular punch, thus leaving islands of skin in the donor area to heal it.  
 skin g., a piece of skin transplanted from one part of the body to another to cover a denuded area.  
 sleeve g., a g. for repairing a severed nerve by connecting central and peripheral ends with a sleeve-like structure.  
 split-skin g., a g. consisting of a part of the thickness of the skin, i.e., all of the epidermis and part of the dermis. See also Blair-Brown g.  
 Stent g., an inlay skin g., or a skin g. held in place by a tie-over dressing.  
 syngenic g., isograft.  
 tendon g., a g. of tendon, as in tendon transplantation.  
 thick-split g., a g. with a thickness of about three-quarters of the skin.  
 Thiersch g., Ollier g.  
 vascularized g., the state of a g. after the recipient vasculature has been connected with the vessels in the g.  
 white g., hyperacute rejection of a skin allograft.  
 Wolfe g., Wolfe-Krause g.; a full-thickness skin g., but without any subcutaneous fat.  
 xenogenic g., a term sometimes used to denote g.'s between animals from phylogenically widely separated species.  
 zooplastic g., zoograft.  
 graft'ing. Transplanting a graft.  
 bone g., osteoplasty (1).  
 Graham, Thomas, English chemist, 1805-1869. See G.'s law.  
 Grubmell'la [G. S. Graham-Smith]. A genus of aerobic, nonmotile microorganisms (order Rickettsiales) containing long or short, rod-shaped, Gram-negative cells which resemble those of *Bartonella* but which are less pleomorphic. These organisms occur within the erythrocytes of lower mammals, but they appear to be nonpathogenic and do not affect the health of the host. The type species is *G. talpae*.  
*G. peromysci*, a species that occurs naturally in the deer mouse.  
*G. talpae*, a species found in the erythrocytes of moles; it is the type species of the genus *G*.  
 Graham, Steell, British physician, 1851-1942. See G.'s marmur.  
 grain [L. *granum*]. 1. Cereal plants; e.g., corn, wheat, rye. 2. A seed of one of the cereal plants. 3. A minute, hard particle of any substance, as of sand. 4 (gr). A unit of weight,  $1/160$  dram,  $1/1013$  avoirdupois ounce,  $1/100$  Troy ounce,  $1/1554$  Troy pound,  $1/1000$  avoirdupois pound, the equivalent of 0.0648 g.  
 g. alcohol, alcohol (2).  
 grains. Hyaline bodies within the horny layer of epidermis, found in keratosis follicularis.  
 Gram, Hans C. J., Danish bacteriologist, 1853-1938. See G.'s iodine, stain; Weigert-G. stain.  
 gram (g). A unit of weight in the metric or centesimal system, the equivalent of 15.432 grains.  
 -gram [G. *gramma*, character, mark]. Suffix denoting a recording, usually by an instrument. Cf. -graph.



3738  
TR

PTO/SB/21 (09-04)  
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<b>TRANSMITTAL FORM</b>	
(to be used for all correspondence after initial filing)	
Total Number of Pages-in-This Submission	29
Application Number	09/782,594
Filing Date	February 12, 2001
First Named Inventor	Bianchi, John R., et al.
Art Unit	3738
Examiner Name	Paul B. Preblich
Attorney Docket Number	RT1 112R/1915-13980US02

**ENCLOSURES (check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment and Response Under 37 CFR §1.111 with Exhibits A-C attached thereto <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Return-Receipt Postcard <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm	McAndrews Held & Malloy, Ltd.
Signature	<i>Donald J. Pochopien</i>
Printed Name	Donald J. Pochopien, Reg. No. 32,167
Date	July 15, 2005

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 07/15/2005.

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**PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)  
FY 2005**

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)

Application Number 09/782,534

Docket Number (Optional)

1615-13680USC2

For "Assembled Implant"

Filed February 12, 2001

Art Unit 3738

Examiner - Paul B. Preblich

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	
<input checked="" type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$120
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$
<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$

☐ Applicant claims small entity status. See 37 CFR 1.27.☐ A check in the amount of the fee is enclosed.☐ Payment by credit card. Form PTO-2038 is attached.☐ The Director has already been authorized to charge fees in this application to a Deposit Account.☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 13-0017. I have enclosed a duplicate copy of this sheet.**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest. See 37 CFR 3.71

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/95).

☒ attorney or agent of record. Registration Number 32,167☐ attorney or agent under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34. \_\_\_\_\_

Signature

Donald J. Pochopien, Reg. No. 32,167

Typed or printed name

July 15, 2005

Date

312-775-8000

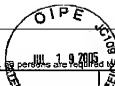
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NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Complete If Known

**FEE TRANSMITTAL**  
**for FY 2005**☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 120.00

Application Number	09/782,594
Filing Date	February 12, 2001
First Named Inventor	Bianchi, John R., et al.
Examiner Name	Paul B. Preblich
Art Unit	3738
Attorney Docket No.	RTI 112R/1915-13980US02

**METHOD OF PAYMENT (check all that apply)**☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 13-0017 Deposit Account Name: **McAndrews Held & Malloy**

For the above-identified deposit account, the Director is hereby authorized to (check all that apply)

☒ Charge Fee(s) indicated below☐ Charge Fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s). ☒ Credit any overpayments  
under 37 CFR 1.16 and 1.17

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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid(\$)
	Fee(\$)	Small Entity Fee(\$)	Fee(\$)	Small Entity Fee(\$)	Fee(\$)	Small Entity Fee(\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee(\$)	Small Entity Fee(\$)
Each claim over 20, or for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	300	180

Total Claims	Extra Claims	Fee(\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee	Fee Paid (\$)
-20 or HP	x	=				
HP = highest number of total claims paid for, if greater than 20						
Indep. Claims	Extra Claims	Fee(\$)	Fee Paid (\$)			
-3 or HP	x	=				
HP = highest number of independent claims paid for, if greater than 3						

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee(\$)	Fee Paid(\$)
-100	/50	(round up to a whole number) x	=	

**4. OTHER FEE(S)**

	Fee Paid(\$)
Non-English Specification, \$130 fee (no small entity discount)	
Other: Petition for Extension Of Time	120.00

**SUBMITTED BY**

Signature	Registration No.	32,167	Telephone	(312)775-8000
Name (print/type)	Donald J. Pochopien	(Attorney/Agent)	Date	32,167

## **EXHIBIT 18**



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490
7590 09/27/2005				
DONALD J. POCHOPIEN McANDREWS, HELD & MALLOY, LTD. CITICORP CENTER, 34TH FLOOR 500 WEST MADISON STREET CHICAGO, IL 60661				
EXAMINER PREBILIC, PAUL B				
ART UNIT 3738		PAPER NUMBER		

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/782,594

Applicant(s)

BIANCHI ET AL

Examiner

Paul B. Prebille

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-34, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-34, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-34 and 60-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 79 of copending Application No. 09/941,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claim 79 is read on by what is set forth in the claims of this application such claim 79 would be "anticipated" thereby. For this reason, the claims are considered obvious in view of claim 79; see *In re Goodman*, *supra*.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis (US 5,147,367). Ellis anticipates the claim language where the bone pieces or bone portions as claimed are the bone portions of the same patient grafted onto the bones they were separated from to form a graft in Ellis; see the figures, the abstract and column 5, lines 12-56. "Graft" is denoted as "anything inserted into something else so as to become an integral part of the latter"; Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, p. 599. For this reason, the separated bone pieces are grafts when this term is given its broadest reasonable interpretation.

With regard to claim 27, the breaks or separations are in cortical bone because cortical bone is on the outside of bone as is visible in the drawings. The pins used are inherently press-fitted into the holes formed because they are held there by a friction tight fit. Without this type of fit, they would not function properly.

With regard to claims 28 and 32, the pins of Ellis are cortical bone pins because they are for cortical bone the same way a "bone screw" is for bone even though it can be made of a metal.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis (US 5,147,367). Ellis discloses using "any number of pins or screws" to secure the bone portions together but not the use of "four" pins as claimed. However, the use of "four" pins would have been considered *prima facie* obvious to an ordinary artisan since Ellis clearly discloses that any number can be used to secure the bone pieces together; see MPEP 2144.04 (VI) (B) that is incorporated herein by reference thereto.

Claims 26, 27, 31-34, and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al (US 5,716,358) in view of Ellis (US 5,147,367). Ochoa discloses bone portions or pieces grafted back onto bones they were separated from but fails to clearly disclose the use of a plurality of pins as now claimed; see Figures 4 and 5 as well as column 6, line 57 to column 8, line 47. However, Ellis teaches that it was known to use a plurality of pins to attach bone pieces together; see *supra*. Therefore, it is the Examiner's position that it would have been obvious to use a plurality of pins in the Ochoa invention in order to better secure the pieces together and for the same reasons that Ellis uses the same.

#### ***Response to Arguments***

Applicants' arguments filed July 19, 2005 have been fully considered but they are not persuasive in all cases.

Applicants argued that the present claims have an effective filing date of parent application 08/920,630 filed August 27, 1997. Due the persuasive arguments and the

amendment to the claims, the Examiner was convinced that the Applicants are correct. The effective filing date of all the claims is considered to be August 27, 1997.

In traversing the prior art rejections, Applicants argue that a "graft" requires that the material used is from a "different site or source." However, the Examiner maintains that the broader definition applied is appropriate because there is no special definition for this term in the specification and because the broader definition is the broadest reasonable one available.

Furthermore, the argument that the material of a graft is from a "different site or source" is not based upon the structure of the device, but rather, it is based upon the source of the material. Since the source of the material is not limiting in the context of the present claims, the argument is considered wholly unpersuasive.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action due to the presentation of new claims 61 and 62. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3738

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilio whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilio  
Primary Examiner  
Art Unit 3738

**Notice of References Cited**

Application/Control No.

09/782,594

Applicant(s)/Patent Under  
Reexamination  
BIANCHI ET AL.

Examiner

Paul B. Prebille

Art Unit

3736

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,192,327	03-1993	Brantigan, John W.	623/17.11
	B	US-5,969,289	11-1999	Coates et al.	623/17.16
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

## **EXHIBIT 19**



ATTORNEY DOCKET NO. RTI 112R /1915-13980US02

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

On the Application of:

Bianchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

Group Art Unit: 3738

Examiner: Paul B. Prebilic

CERTIFICATE OF MAILING

I hereby certify that this document and all documents referred to herein are being sent by first class mail, postage prepaid, to the Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

November 21, 2005

Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants

REQUEST FOR CONTINUED EXAMINATION (RCE)  
UNDER 37 CFR § 1.114

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of 09/27/05 (hereinafter "the Official Action"), finally rejecting all claims (claims 26-34, 61 and 62) and for which a response is due 12/27/05, the Applicants respond as follows:

Amendments to the Claims:

Pages 2-4

Remarks:

Pages 5-16

11/25/2005 DTESSEM1 00000031 130017 09782594

01 FC:1801 790.00 DA

## Amendments to the Claims:

Please substitute the listing of the claims as provided below for any prior listings:

### Claims 1-25 (Cancelled)

26. (currently amended) An assembled bone graft, comprising: a plurality of allograft bone portions layered to form a graft unit, and biocompatible-pins traversing said graft unit for holding said graft unit together as an assembled bone graft, said assembled bone graft being suitable for implantation into a human patient and does not comprise an adhesive.

27. (currently amended) An assembled bone graft comprising:  
two distinct bone portions of cortical bone, and biocompatible pins, wherein said two distinct bone portions are allograft bone processed to be suitable for implantation in a human patient, said biocompatible pins are of appropriate diameter and press fitted into machined holes in said two bone portions to hold together said two bone portions to form said an assembled bone graft suitable for implantation in humans.

28. (currently amended) An assembled bone graft comprising two or more connected, distinct, bone portions of allograft bone forming a graft unit, and cortical bone pins, said two or more connected, distinct, bone portions having holes therein for receiving said cortical bone pins, said cortical bone pins keeping said two or more connected, distinct, bone portions aligned and connected to form an assembled bone graft free of an adhesive suitable for implantation in humans, ~~without an adhesive~~.

29. ((previously presented) The assembled bone graft of claim 28 where there are two connected, distinct, bone portions.

30. ((previously presented) The assembled bone graft of claim 28, wherein said two or more connected, distinct, bone portions are selected from the group consisting of: cortical bone and cancellous bone.

31. (currently amended) An assembled bone graft, comprising:

a first bone portion having holes therein;  
a second bone portion having holes therein aligned with the holes in said first bone portion, said first bone portion and said second bone portion being allograft bone suitable for implantation into a human patient; and  
cortical bone pins press-fitted in said holes for holding said first bone portion in juxtaposition to said second bone portion and forming a said assembled bone graft unit suitable for implantation into a human patient.

32. (currently amended) An assembled bone graft, comprising:  
a first cortical bone portion having a hole therein;  
a second cortical bone portion having a hole therein, said hole in said second cortical bone portion aligning with said hole in said first cortical bone portion, said first bone portion and said second bone portion being allograft bone suitable for implantation into a human patient;  
a cortical bone pin press-fitted in the hole between said first cortical bone portion and said second cortical bone portion to form said assembled bone graft suitable for implantation into a human patient.

33. (currently amended) An assembled bone graft, comprising:  
a first cortical bone portion having holes therein;  
a second cortical bone portion having holes therein aligned with the holes in said first bone portion, said first bone portion and said second bone portion being allograft bone suitable for implantation into a human patient; and  
cortical bone pins press-fitted in said holes for holding said first cortical bone portion in stacked juxtaposition to said second cortical bone portion and forming a graft-unit without an adhesive said assembled bone graft suitable for implantation into a human patient.

34. (currently amended) An assembled bone graft, comprising:

a first bone portion;

a second bone portion provided on said first bone portion to form a graft unit, said first bone portion and said second bone portion being allograft bone suitable for implantation into a human patient; and

~~one or more~~ biocompatible pins inserted into said first bone portion and said second bone portion for holding together said graft unit to form said assembled bone graft suitable for implantation into a human patient.

35-60. (cancelled)

61. (New) The assembled implant of claim 31 wherein said cortical bone pins are four cortical bone pins.

62. (New) The assembled implant of claim 33 wherein said cortical bone pins are four cortical bone pins.

## REMARKS

The amendments to the claims do not add new matter. The amendments to the claims are consistent with the disclosure in the specification and in the priority application USSN 08/920,630, filed 08/27/97, now abandoned. In particular, support for the bone being "allograft" bone is found in priority application USSN 08/920,630 at page 2, lines 21-22 ("the implant is derived from allograft or autograft cortical bone sources. . . ."). Support for the assembled graft being chemically "treated" so as to be "suitable for implantation into humans" is found in priority application USSN 08/920,630 at page 3, lines 23-25 ("so that the finished product may be treated by standard techniques known in the art (alcohol, peroxide, or like treatments), prior to storage and shipment to physicians for use in implantation procedures."); and at page 18, lines 28-29 ("Following implantation, the recipient (whether human or animal) is monitored for implant stability and success in fusion.").

For all these reasons, the amendments to the claims do not add new matter.

### Summary of the Bases for Objection/Rejection

Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154.

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis).

Claims 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis).

Claims 26, 27, 31-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis).

Each of these four (4) bases for rejection are addressed in Sections I-IV, respectively, which follow.

## I. Obviousness Type Double Patenting

Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154. The attorney for the common assignee of both pending applications is cofiling with this response an appropriate terminal disclaimer. Accordingly, this basis for provisional rejection has been rendered moot.

## II. 35 U.S.C. § 102(b) over U.S. Pat. 5,147,367 (Ellis)

### A Ellis does not teach or suggest a “graft” as the term is understood in the art

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, “Ellis anticipates the claim language where the bone pieces or bone portions of the **same patient are grafted back onto the bones they were separated from** to form a graft. . . .” [Official Action at page 3, citing Ellis at the figures, the abstract, and column 5, lines 12-56; emphasis added in bold.] The word “graft” never appears in Ellis and it is for a good reason. As a person skilled in the art, Ellis knew that he was not “grafting” when he re-attached a fragment of bone to the **same** site from which it fractured. In the bolded language above, the Patent Office acknowledges that Ellis discloses binding the bone back to the location that it was “**separated from,**” i.e., the **same** location. Also in FIGs 2a-2d and FIGs. 3 and 4 of Ellis, Ellis discloses binding a “bone fragment” to the **same** “bone mass” from which it separated. [See the discussion in Ellis at col. 5, lines 40-42.] As support for the Patent Office’s position that the separated “bone fragment” of Ellis is a “graft,” the Patent Office cites to Stedman’s Medical Dictionary, 23<sup>rd</sup> Edition at page 599 for the definition of “graft” as “anything **inserted** into something else so as to become an integral part of the latter.” [Official Action at page 4; emphasis added in bold.] **Applicants request a copy of this cited page so that they can see the full definition in its full context.** However, the definition upon which the Patent Office relies misses the fine part of the definition which requires that the “anything” come from a “**different site or source.**” As support for the Applicants’ position, the Applicants cite to the following three medical dictionaries, including Stedman’s (24<sup>th</sup> Edition), the successor of the Edition relied

upon by the Patent Office, which did include the specific definition of the term "**bone graft**" which is the exact term in Applicants' claims:

**graft** - a tissue or an organ taken from a site or a person and inserted into a new site or person, performed to repair a defect in structure.

[Exhibit A of response to the Official Action of 03/24/05: Mosbey's Medical, Nursing and Allied Health Dictionary, The C.V. Mosbey Co., St Louis, 1990, Eds. Glanze, et al., at page 531 ; emphasis added in bold.]

\* \* \*

**grafting** - The implantation of skin or other tissue, from a different site or source, to replace damaged tissue.

[Exhibit B of response to the Official Action of 03/24/05: Dorland's Illustrated Medical Dictionary, W.B. Saunders & Co., 24th Edition, Philadelphia, 1965, at page 629; emphasis added in bold.]

\* \* \*

**bone graft** - bone transplanted from a donor site to a recipient site.

[Exhibit C of response to the Official Action of 03/24/05: Stedman's Medical Dictionary, 24<sup>th</sup> Edition, Williams & Wilkins, Baltimore, 1982, at page 604, emphasis added in bold.]

Thus, the art as a whole, including the Stedman's dictionary, such as relied upon by the Patent Office, recognizes that a "graft," and particularly a "**bone graft**" is tissue that comes from a "**different site or source.**" Further, the Patent Office's reliance upon a general definition of a "graft" taken out of context, when a specific definition of a "**bone graft**" is likely present is legal error. *See e.g., In re Lunsford*, 148 USPQ 721, 724 (CCPA 1966) (reversing the Board's conclusion of obviousness where the board relied on the "general" teachings of the prior art while ignoring the "specific" teachings, stating: "Thus, the Examiner erred in ignoring the specific teachings of the primary references **without references containing specific teachings demonstrating that the specific teachings in Biel I and III could be ignored.**"); *In re Fournet*, 148 USPQ 740, 742 (CCPA 1966) ("We regard the use of the prior art teachings under 35 U.S.C. § 103 as a two-way street available to both parties. We

are required to evaluate the references *as a whole* regardless of the party offering the references. In Lunsford, we refuse to ignore **specific teachings which we believed would be given greater weight than general teachings by one of ordinary skill in the art.**" [emphasis added in bold]. If Applicants did the same, it would be grounds for inequitable conduct. **Hence the Applicants renew their request for a copy of cited page 599 from Stedman's Medical Dictionary, 23<sup>rd</sup> Edition.**

In addition, the definition of "graft" relied upon by the Patent Office recites as follows: "anything **inserted** into something else so as to become an integral part of the latter." [Official Action at page 4; emphasis added in bold.] Consistent with the definition above, the word "inserted" means that something came from the outside. However, the bone fragment that is being re-attached to the patient never came from the outside or somewhere else, so as to be inserted. Rather, it came from **inside** the patient to be affixed to the **same** location from where it originated.

In response to the Applicants' evidence and arguments above, the Patent Office contends that "there is no special definition for this term [i.e., "graft"] in the specification." [Official Action at page 5.] The Applicants disagree. The Applicants' specification uses the term "autograft" in its ordinary sense to mean donor tissue from the same patient to be treated, but wherein the tissue comes from a "**first**" donor site that differs from a "**second**" recipient site:

The goal is best achieved by using **autograft bone from a first site for implantation into a second site.** However, use of **autograft** material is attended to by the significant disadvantage that a **second site of morbidity must be created** to harvest autograft for implantation into a first diseased or injured site.

[Specification at page 1, line 29 to page 2, line 1; emphasis added in bold.]

Thus, the Applicant's specification use the term "graft" and "bone graft" as indicative of something from another site, consistent with the dictionary definitions above. More importantly, the art recognizes that "allograft" bone is non-living bone that has been processed to remove

Further, the art has long recognized, as evidenced by issued U.S. patents in the present art, which patents are consistent with Applicants' dictionary definitions, that from the past through the present, a graft is a **"replacement"** item as opposed to the repair of an existing item:

The term **"graft"**, as used herein, refers to a natural or synthetic implantable **substitute** for various kinds of tissue.

[Exhibit D: U.S. Pat. 5,916,216, filed 11/04/96 at col. 1, lines 59-61; emphasis added in bold.]

\* \* \*

Where the term **"graft"** is used, **those skilled in the art will recognize** that this implies that a portion of a physiological passage is **replaced** or interconnected to other such passages by means of the implant.

[Exhibit E: U.S. Pat. 6,290,718, filed 02/02/98, at col. 6, lines 9-12; emphasis added in bold.]

Thus, the relevant art, like the dictionary definitions, considers a graft to be a **"replacement"** or a **"substitute"** (which means that it comes from somewhere else) and not a **"repair"** of the existing parts. By analogy, if you took your car to the dealer and they **replaced** your engine, it would be different than if they **repaired** your engine.

Accordingly, when Ellis discloses binding a fractured **"fragment of bone"** back to its original bone mass, the fragment is not a **"graft"** because the broken piece of bone is from the **same** fracture site, rather than a **different** site. . It is not from a **"different site or source"** or from a **"donor site,"** that is intended for a second recipient **"site."** For all these reasons, claims 26-28, 30-31 and 33-34 are not anticipated by U.S. Pat. 5,147,367 (Ellis) under 35 U.S.C. § 102(b).

#### **B. Ellis does not teach or suggest the use of **"allograft bone"****

Although the above arguments of record alone are sufficient to overcome the Examiner's rejection, the Applicants have amended independent claims 26-28 and 31-34 to facilitate the prosecution on the merits. In particular, the Patent Office correctly points out

that Ellis discloses "bone pieces or bone portions of the **same** patient are grafted back **onto the bones they were separated from** to form a graft. . . ." [Official Action at page 3.] Assuming for the sake of argument that these bone portions are "grafts," one skilled in the art recognizes that this bone from the **same** patient is called an "autograft." More importantly, in Ellis, this bone which from the same patient and the same site as the fracture is inherently "**living bone**" that is filled with living cells.

In contrast, the Applicants have amended each of independent claims 26-28 and 31-34 to reflect that the bone of the claims is "allograft " bone. One skilled in the art recognizes that "allograft" bone, which by definition comes from a **different member** of the same species, are **non-living bone** that has been chemically and physically processed to remove fat, viruses (such as HIV), foreign protein, bone marrow and cells which might induce an immune response or rejection of the graft in the recipient, thereby making it suitable for implanting in a human patient. [See Exhibit F: U.S. Pat. 5,556,379 (Wolfenbarger), "Process for Cleaning Large Bone Grafts and Bone Grafts Produced Thereby," filed 02/27/95, issued 09/17/96, at col. 1, line 25 to col. 3, line 11.] Likewise, U.S. Pat 5,513,662, entitled "Preparation of bone for transplantation," which issued TO Morse on 05/07/96, discloses as the Background, the need in allograft bone of decontaminating to remove pathogens and cleaning to remove antigens (immunogens), to render the allograft bone suitable for implanting into a human patient:

The present invention relates to methods of processing bone for transplantation. More particularly, the invention is directed to the provision of decontaminated bone, transplant of which **minimizes substantially exposure of the transplant recipient to contaminating pathogens or immunogenic material.**

#### REPORTED DEVELOPMENTS

The procurement and processing of **human bone for transplantation** is a complicated task which requires the coordinated efforts of several groups including the donor's family, the hospital staff, the local procurement group, the blood specimen processing laboratory, the **bone processing** laboratory, the transplant patient, and the transplant team.

A **prime consideration** is minimization of the risk of **transferring potentially harmful diseases to tissue recipients.** In fact,

provision of **bone tissue safe for transplantation** provides a very special challenge as **immunogenic material and also microorganisms and viruses** can be found deep within the **internal matrix of bone samples**.

In this regard, blood samples may be analyzed at the processing laboratory for a variety of known infectious agents including, for example,

Human immunodeficiency virus (HIV-1)

Human immunodeficiency virus (HIV-2)

Human T cell lymphotropic virus (HTLV-1)

Hepatitis B

Hepatitis C

Cytomegalic virus (CMV)

Treponema pallidum (syphilis).

With respect to the serious clinical consequences resulting from the transplanting of contaminated bone see, for example, Kakaiya et al., "Tissue transplant-transmitted infections," Transfusion 31 (3), 1277-284, 1991; Shutkin, "Homologous-serum hepatitis following use of refrigerated bone-bank bones, report of a case", Journal of Bone and Joint Surgery, 16-A(1), 160-162, 1954. Transmission of human immunodeficiency virus (HIV) via bone as well as bone marrow has also been reported. "Transmission of HIV through bone transplantation case report and public health recommendations" Novbid. Mortal. Weekly Rep., 37, 597-599, 1988; Furlini et al., "Antibody response to human immunodeficiency virus after infected bone marrow transplant", Eur. J. Clin. Microbiol. Infect. Dis. 7(5) 554-665, 1988. HIV has been cultured from fresh as well as refrigerated bone and freeze-dried bone. Buck et al. "Human immunodeficiency virus cultured from bone. Implications for transplantation", Clin. Ortho., 251, 249-253, 1990. Additionally, protection of technicians at the bone processing laboratory is of great concern because of the serious potential for transmission of HIV and hepatitis B.

A further and **very important consideration** with respect to the design of bone processing methodologies is **avoiding or minimizing immune response (including transplant rejection)**

in the recipient patient to donor macromolecules remaining in the transplanted bone, such as collagens, and cell surface antigens of the major histocompatibility complex or other glycoproteins. See, for example, Friedlander and Horowitz, *Orthopedics*, 15(10), 1171-1175 (1992), and Mankin, et al., *Id.*, at 1147-1154.

Accordingly, there is a **great need for bone processing methods that decrease the risk of recipient immunological response or disease transmission associated with the use of, and preparation and procurement of, transplantable bone.** In this regard it is also important to recognize that even if state of the art donor screening methodology is used, recent infections in a particular donor may not be detected, thereby underscoring the importance of improved cleaning and decontaminating treatments that offer prophylactic protection against potential, or as yet undetected, infectious agents.

The combination of donor screening and antibiotic treatments traditionally employed during bone processing reduces, but do not limit to an acceptable level, the risk of transmission of known viral contaminants and a variety of bacteria. See, for example, Scarborough, N. L., *Orthopedics*, 15(10), 1161-1167 (1992), and Malinin, T. I., "Acquisition and Banking of Bone Allografts", in *Bone Grafts and Bone Substitutes*, Habal and Reddi, eds., Chapter 19, pp. 206-225, W. B. Saunders Company, Philadelphia, Pa. (1992). As aforementioned, currently-available methods offer no prophylactic protection from viruses, select bacteria, and fungi which are common flora in humans or in a hospital environment. Although the sensitivity and specificity of screening tests for such pathogens are high, screening tests are not foolproof, and false negatives may result from, for example, low antibody levels (e.g., recent infection or immunodeficiency) or even technician error. Furthermore, screening tests may be useful only to identify known infectious agents. Additionally, the aforementioned traditionally-used antibiotic antibacterial cocktails currently in use do not readily kill all types of bacteria. For example, a commonly used polymyxin/bacitracin solution (50,000 units bacitracin/500,000 units polymyxin B) does not inactivate *Proteus* species. Furthermore, traditional antibiotic cocktails have no significant effect on viruses or fungi.

There are also significant limitations on the extent to which decontaminating agents have been used successfully to penetrate and to decontaminate matrix of bone. See Prolo and Oklund, "Sterilization of Bone by Chemicals", in *Osteochondral Allografts: Biology, Banking and Clinical Applications*, Friedlaender et al.,

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eds., Chapter 22, pp. 233-238, Little, Brown and Company, Boston, Mass. (1983). **Bone matrix contains potentially removable materials, for example, marrow, cells and lipid that impede access of decontaminating agents deep into bone matrix where, as aforementioned, infectious agents or immunogenic macromolecules may be present.**

Certain of the difficulties encountered in extracting removable materials from the bone matrix are described, but not resolved, according to Great Britain Patent Specification 964,545, published in 1964.

The '545 Specification describes a procedure for using a **fat solvent** (for example, a chloroform/methanol mixture) for cleaning of bone. Substantial periods of time are involved that are inconsistent with preferred bone banking procedures, such as to rapidly match a donor bone piece of appropriate size for a recipient. An additional disadvantage stated to be inherent in this methodology is that it appears to be restricted to a particular series of steps that must be performed in a particular order. If this is not done, **immunogenic donor proteins are stated to remain in the bone owing to in situ denaturation thereof caused by the fat solvent.**

These and other difficulties associated with the **provision of decontaminated bone suitable for transplantation** are resolved according to the practice of the invention.

[Exhibit G: U.S. Pat. 5,513,662, at col. 1, line 12 to col. 3, line 5; emphasis added in bold]

Consistent with the well-know understanding in the art that "allograft" bone must be cleaned and non-living, the Applicants' specification discloses a process for tissue "cleaning" and "decontamination":

In developing the various embodiments of the present invention, one technical issue of merit is the need to develop a process whereby donor tissue, whether hard or soft tissue, **allograft or xenograft** tissue, may be treated in such a fashion as to **eliminate the possibility of cross contamination between tissue segments obtained from different sources.** While it is possible to practice the present invention to advantage using tissue obtained from a single screened donor, the real economies of scale and commercially viable application of the present technology is best

realized by implementation of an efficient and reliable **tissue decontamination process**. Ideally, the process is one which permits multiple segments of soft or hard tissue to be treated simultaneously so that a stock of materials for assemblage of implants according to the present invention is facilitated. Accordingly, on preferred method for treatment of tissue, disclosed in PCT publication WO 00/29037, the disclosure of which is hereby incorporated herein by reference as if fully set forth herein (and priority of the US Patent filings which gave rise to this application is hereby claimed for that purpose). Accordingly, in this aspect of the invention, a process is claimed whereby an **assembled allograft or xenograft tissue implant** is prepared by **treating** the tissue in a closed container in which **different cleaning solutions** are contacted with the implant segments, either before or after assembly and machining into the final implant form, either in the presence or absence of sonication, with rapid oscillation of pressure in the closed container, **to achieve deep cleaning** and interpenetration of cleaning solvents into the interstices of porous implants or tissues. Solutions including, but not limited to **detergent solutions, peroxide solutions** and the like are used in such procedure, and **terminal sterilization with gamma irradiation**, gaseous sterilants known in the art or other terminal sterilization procedures known in the art are employed to ensure safe implantation of the assembled implants according to this invention.

[Specification at page 8, lines 6-29; emphasis added in bold.]

Thus, when the applicants claim as an element “allograft bone” to produce an assembled graft that is suitable for implanting in a human patient,” the allograft bone was inherently cleaned and decontaminated so as to be **“non-living”** and free of foreign proteins, bacteria and viruses. For these reasons, the allograft bone employed in the Applicants’ invention is structurally different than the **living** bone that is being repaired in Ellis

By analogy, one cannot claim a DNA molecule because it would read on a product as found in nature. However, one can claim the “isolated and purified DNA molecule.” Likewise, in the present case, any allograft bone that is “suitable for implantation into a human patient” has been cleaned and isolated and is inherently non-living (like a natural sponge found in the grocery store as opposed to a sponge picked fresh from the ocean seabed). For these reasons, claims 26-28 and 31-34 and their dependents (claims 29-30) are

neither anticipated by Ellis, nor would they have been obvious over Ellis as of their earliest claimed priority date (August 27, 1997).

**C. Ellis does not teach or suggest an “assembled implant suitable for implantation into a human patient”**

Separately, each of independent claims 26-28 and 31-34 have been amended to recite that the “assembled” bone graft is “suitable for implantation into a human patient.” See the Specification at page 8, lines 19-29. As a result, the claimed bone graft of the Applicants’ invention must be in an “assembled” form outside the body, so as to be suitable (in assembled form) for implantation into the body. In contrast Ellis fails to teach any bone graft (or implant) that is assembled outside the body. To the extent that Ellis can be said to teach anything that is assembled, the actual assembly of any bone occurs in the body of which living bone and living bone fragments in the human body are an integral part of the assembly. Ellis teaches a surgical repair technique (using pins or screws to resecure a living bone fragment back to its original location). Ellis never teaches or suggests an “assembled bone graft” having a separate existence in “assembled” form outside the patient so as to be “suitable for implantation into a human patient.” For this separate reason, claims 26-28 and 31-34 and their dependents (claims 29-30) are neither anticipated by Ellis, nor would they have been obvious over Ellis as of their earliest claimed priority date (August 27, 1997).

**III. 35 U.S.C. § 103(a) over U.S. Pat. 5,147,367 (Ellis)**

Claims 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, “Ellis discloses using ‘any number of pins or screws’ to secure the bone portions together but not the use of ‘four’ pins as claimed.” [Official Action at page 4.] The Patent Office then contends that “the use of ‘four’ pins would have been considered *prima facie* obvious to an ordinary artisan. [Official Action at page 4.] The Applicants respectfully submit that the cited reference fails to make a *prima facie* case of obviousness against the presently claimed invention.

As an initial matter, claims 61 and 62 are ultimately dependent upon claims 31 and 33, respectively. As discussed in Section II *supra*, independent claims 31 and 32 include

as an element bone portions of “allograft” bone, which are is processed and non-living in order to be “suitable for implantation into humans.” In contrast in Ellis, the fragment of bone that is re-attached to the site from which it fractured is “living” bone. One skilled in the art recognizes that the “living” autograft bone of Ellis is structurally different than the dead and highly processed “allograft” bone of the Applicants’ invention. Thus, even if Ellis could be construed as suggesting the use of 4 pins, Ellis would not have rendered obvious the Applicants’ invention as a whole because Ellis never taught or suggested the use of dead and processed tissue, and particularly not “allograft.”

Separately, Ellis never teaches or suggests a graft that is “assembled” outside the body so as to be “suitable for implantation into the body.” Rather in Ellis, the only “assembled bone” exists exclusively in the body because the main bone mass to which a fragment is re-attached is part of the living human body.

For any one of these reasons, claims 61-62 would not have been obvious over the disclosure in Ellis.

#### IV. 35 U.S.C. § 103(a) over U.S. Pat. 5,716,358 (Ochoa) in view of Ellis

Claims 26-27, 31-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, “Ochoa discloses bone portions or pieces **grafted back onto the bones they were separated from . . .**” [Official Action at page 4, citing Ochoa at Figures 4 and 5, and column 6, line 57 to col. 8, line 47; emphasis added in bold.] In the bolded language above, the Patent Office acknowledges that Ochoa discloses binding the bone back to its **original** location (*i.e.*, the location that it was “separated from”). In the same sentence, the Patent Office admits that Ochoa “**fails to clearly disclose the use of a plurality of pins as now claimed.**” [Official Action at page 4; emphasis added in bold.] To make up for this admitted deficiency, the Patent Office cites to Ellis for allegedly disclosing that “it was well known to use a plurality of pins to attach bone pieces together.” [Official Action at page 4; emphasis added in bold.] The Applicants respectfully submit that the cited combination fails to make a *prima facie* case of obviousness against the presently claimed invention.

In particular, each of independent claims 26-27 and 31-34 have been amended to recite that the bone portions therein are "allograft" bone. Because the claimed grafts are also "suitable for implantation in humans," the "allograft" bone of the claims is **non-living** and has been processed to remove fat, proteins, and cells, the latter two which would be recognized as foreign and rejected by the graft recipient. Unless "allograft" bone is non-living and has been processed to remove foreign antigens (i.e., proteins and cells) it would not be suitable for use in humans. In marked contrast, both Ochoa and Ellis, as acknowledged by the Patent Office, teach how to repair a patient's own bone inside his body. In particular, Ochoa and Ellis teach how to re-attach a fractured fragment of **living** bone back to its original **living** bone mass. Neither Ochoa nor Ellis discloses or suggest the use of "allograft" bone. For this reason alone, the combination of Ochoa and Ellis would fail to make a *prima facie* case of obviousness against claims 26-27 and 31-34 or their dependents (claims 61 and 62).

Separately, each of the Applicants' claims is directed to an "assembled bone graft" that is "suitable for implantation into a human patient." Thus, the "assembled" bone graft must exist in "assembled" form **outside** the body of a human patient to be "suitable for implanting into a human patient." In contrast, in both Ochoa and Ellis, the "assembled" bone species only exists in "assembled" form **inside** the body of the human patient because it is assembled *in vivo*. Hence, at no time does Ochoa or Ellis teach or suggest an "assembled" bone graft (that exists in assembled form outside the body) so as to be "suitable for implantation into a human patient." For this reason also, the combination of Ochoa and Ellis would fail to make a *prima facie* case of obviousness against claims 26-27 and 31-34 or their dependents (claims 61 and 62).

## SUMMARY

Claims 26-34 and 61-62 are pending and subject to rejection.

In view of the evidence, arguments and/or amendments herein, the rejection of claims 26-34 under 35 U.S.C. § 102 (b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot. In view of the evidence, arguments and/or amendments herein, the rejection of claims 61-62 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot.

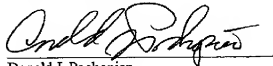
In view of the evidence, arguments and/or amendments herein, the rejection of claims 26-27, 31-34 and 61-62 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot.

Claims 26-34 and 61-62 are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:




Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8133

Date: November 21, 2005

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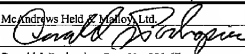
Under the Paperwork Reduction act of 1996, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

	<b>TRANSMITTAL FORM</b>	
	Application Number	09/782,594
	Filing Date	February 12, 2001
	First Named Inventor	Bianchi, John R., et al.
	Art Unit	3738
	Examiner Name	Paul B. Prebille
Total Number of Pages in This Submission		85
		Attorney Docket Number RTI 112R/1915-13980US02

**ENCLOSURES (check all that apply)**

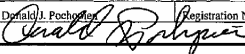
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> Request For Continued Examination (RCE) Under 37 CFR § 1.114, with Exhibits D-G attached <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Return-Receipt Postcard <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm	McAndrews Held & Malloy, Ltd.
Signature	
Printed Name	Donald J. Pochopien, Reg. No. 321,67
Date	November 21, 2005

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450 on 11/21/2005

Name (Print/type)	Donald J. Pochopien	Registration No. (Attorney/Agent)	32,167
Signature		Date	11/21/2005

## **EXHIBIT 20**



# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490
7590 02/27/2006				
DONALD J. POCHOPIEN McANDREWS, HELD & MALLOY, LTD. CITICORP CENTER, 34TH FLOOR 500 WEST MADISON STREET CHICAGO, IL 60661				
EXAMINER PREBILIC, PAUL B				
ART UNIT 3738 PAPER NUMBER				
DATE MAILED: 02/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. 09/782,594	Applicant(s) BIANCHI ET AL.	
Examiner Paul B. Prebille	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-34, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-34, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB-08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 7, 2005 has been entered.

***Claim Objections***

Claims 33, 61, and 62 are objected to because of the following informalities:

In claim 33, on lines 7-9, the language "and forming without an adhesive said assembled bone graft suitable for implantation into a human patient" is grammatically awkward. The Examiner suggests inserting commas around the phrase "without an adhesive" in order to overcome this objection.

In claims 61 and 62, the status identifiers are improper since these claims were previously presented. This amendment has been entered but future amendments may be deemed non-compliant under 35 USC 121, if improper status identifiers are used. Appropriate correction is required.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-34 and 60-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 79 of copending Application No. 09/941,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claim 79 is read on by what is set forth in the claims of this application such claim 79 would be "anticipated" thereby. For this reason, the claims are considered obvious in view of claim 79; see *In re Goodman, supra*.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis (US 5,147,367). Ellis anticipates the claim language where the bone pieces or bone portions as claimed are the bone portions of the same patient grafted onto the bones

they were separated from to form a graft in Ellis; see the figures, the abstract and column 5, lines 12-56. "Graft" is denoted as "anything inserted into something else so as to become an integral part of the latter"; Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, p. 599. "Allograft" is a homograft (i.e. from the same species) that is allogenic (i.e. genetically distinct) to the recipient; see Merriam-Webster OnLine at [www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft](http://www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft). Since the bone of Ellis is capable of being used as a bone graft unit upon the death of the individual, it is considered an allograft bone portion with respect to another human being to the extent that this language can be given patentable weight. The site of source of the material is relative to how it can be used and is not indicative of the material itself because the pieces of Ellis are allogenic with respect to another human being. For these reasons, the separated bone pieces are grafts and allografts when these terms are given their broadest reasonable interpretation.

With regard to claim 27, the breaks or separations are in cortical bone because cortical bone is on the outside of bone as is visible in the drawings. The pins used are inherently press-fitted into the holes formed because they are held there by a friction tight fit. Without this type of fit, they would not function properly.

With regard to claims 28 and 32, the pins of Ellis are cortical bone pins because they are for cortical bone the same way a "bone screw" is for bone even though it can be made of a metal.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis (US 5,147,367) alone. Ellis discloses using "any number of pins or screws" to secure the bone portions together but not the use of "four" pins as claimed. However, the use of "four" pins would have been considered *prima facie* obvious to an ordinary artisan since Ellis clearly discloses that any number can be used to secure the bone pieces together; see MPEP 2144.04 (VI) (B) that is incorporated herein by reference thereto.

Claims 26, 27, 31-34, and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al (US 5,716,358) in view of Ellis (US 5,147,367). Ochoa discloses bone portions or pieces grafted back onto bones they were separated from but fails to clearly disclose the use of a plurality of pins as now claimed; see Figures 4 and 5 as well as column 6, line 57 to column 8, line 47. However, Ellis teaches that it was known to use a plurality of pins to attach bone pieces together; see *supra*. Therefore, it is the Examiner's position that it would have been obvious to use a plurality of pins in the Ochoa invention in order to better secure the pieces together and for the same reasons that Ellis uses the same.

Claims s 26-34 and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation. However, Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6). Coates, however, teaches that is was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner's position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

#### ***Response to Arguments***

Applicants' arguments filed November 23, 2005 have been fully considered but they are not persuasive in all cases.

Applicants state that they filed a terminal disclaimer in order to overcome the double patenting rejection. However, upon review of the response including the transmittal, there is no evidence that one was filed. For this reason, the rejection has been maintained.

Applicants traverse the rejection utilizing Ellis by arguing that Ellis does not disclose a "graft" because the bone pieces are not from a different site or source. This has not been found persuasive because this argument is not based upon a structural difference, but rather, relies solely on where the material is obtained instead of a structural difference. In other words, the argument that the material of a graft is from a "different site or source" is not based upon the structure of the device, but rather, it is based upon the source of the material. Since the source of the material is not limiting in the context of the present claims, the argument is considered wholly unpersuasive.

Furthermore, the Examiner maintains that the broader definition applied is appropriate because there is no special definition for this term in the specification and because the broader definition is the broadest reasonable one available; the Examiner has included a copy of the definition from Stedman's Medical Dictionary utilized in the previous Office action.

Next, Applicants argue that the term "allograft" inherently means that the tissue has been chemically and physically processed into a non-living material that is said to be suitable for implantation. Although the art does process some allogenic materials for implantation, it is not inherent that all allografts are processed because there are clearly some allografts that are not processed; see, for example, US-20030077825 in paragraph [0024], US-20030036800 in paragraph [0007], and US-6,398,786 on column 1, lines 39-44 (see MPEP 2112.01 that is incorporated herein by reference). For this reason, the Examiner asserts that "allograft" merely indicates where the tissue is

obtained and how it is intended to be used and not on any clear structural feature of the material. For these reasons, the rejections have been maintained.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Preblich whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Preblich  
Primary Examiner  
Art Unit 3738

# **Notice of References Cited**

Application/Control No.

09/782,594

Applicant(s)/Patent Under  
Reexamination  
BIANCHI ET AL.

Examiner

Paul B. Preblich

Art Unit

3738

Page 1 of 1

## **U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,398,786	06-2002	Sesic, Nenad	606/73
*	B	US-2003/0036800	02-2003	Meredith, Thomas L.	623/23.63
*	C	US-2003/0077825	04-2003	Bhatnagar et al.	435/395
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

## **FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	EP-0517030 A2	05-1992	EP	Siebels et al	A61F 2/44
	O					
	P					
	Q					
	R					
	S					
	T					

## **NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)			
	U	Copy of Merriam-Webster OnLine definitions for allograft <a href="http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&amp;va=allograft">http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&amp;va=allograft</a>			
	V	Copy of Merriam-Webster OnLine definitions for allograft <a href="http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&amp;va=allogenic">http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&amp;va=allogenic</a>			
	W	Stedman's Medical Dictionary, The Williams & Wilkins Company, 23 <sup>rd</sup> Edition, (c) 1976. p.599.			
	X				

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(e) )  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



Europäisches Patentamt  
European Patent Office  
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Veröffentlichungsnummer: 0 517 030 A2

①

# EUROPÄISCHE PATENTANMELDUNG

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③ Int. Cl.: A61F 2/44

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⑥ Veröffentlichungstag der Anmeldung:  
09.12.92 Patentblatt 92/50

⑦ Bevandte Vertragsstaaten:  
CH DE FR GB IT LI

⑧ Anmelder: MAN Ceramics GmbH  
Wertstrasse 17, Postfach 13 60  
W-6360 Deggendorf (DE)

⑨ Erfinder: Siebels, Wolfgang  
Spitzwegstrasse 4  
W-8360 Deggendorf (DE)  
Erfinder: Ascherl, Rudolf, Dr.  
Türkenstrasse 52  
W-8000 München 40 (DE)

⑩ Wirbelkörperimplantat

⑪ Als Implantat für Wirbelsäulen wird eine Scheibe (11) vorgeschlagen, die alleine oder zu mehreren gestapelt (11 bis 14) zwischen Wirbelkörper einsetzbar sind. Einzelne Scheiben werden nach Bedarf von einem Stang abgeschnitten, wobei die Scheibendicke dem Einzelfall genau angepaßt werden kann. Diese Implantate eignen sich insbesondere für Halswirbel sowie als Ersatz nach der Entfernung von Bandscheiben. Für die Bildung eines Implantats aus mehreren übereinandergestapelten Scheiben kann ein entsprechendes Sortiment von Scheiben bereitgestellt werden, die sich sowohl im Durchmesser als auch in der Höhe unterscheiden. Für den jeweiligen Anwendungszweck werden demzufolge Scheiben mit entsprechender Dicke ausgesucht und zusammengestellt, so daß sie insgesamt die erforderliche Höhe des Implantats ergeben. Verschraubungen und insbesondere längere Handhaben im eingesetzten Zustand des Implantats sind bei dem erfindungsgemäßen Implantat nicht erforderlich.

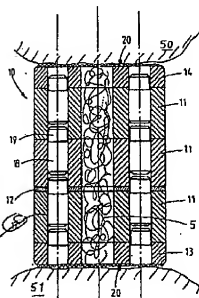


Fig. 1

EP 0 517 030 A2

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Auch die Scheibenpackungen können als Ringscheiben ausgebildet werden, wobei der Hohlraum zur radialen Verankerung der Ringe mit Knochenmaterial oder -zement ausgefüllt werden kann. Vorteilhaft ist es, wenn der Innenmantel der Ringscheiben unregelmäßig ist oder geometrische Unregelmäßigkeiten aufweist. Jede Abweichung von der kreiszylindrischen Form dient zur drehsicheren Verankerung der aufgestapelten Scheiben, wenn der Hohlraum der Ringscheiben mit einem härtenden Material ausgefüllt wird.

Für den sicheren Halt der als Scheibenstapel ausgebildeten Implantats zwischen den angrenzenden Wirbelkörpern werden Endscheiben mit einer rauen Stirnseite vorgesehen. Die Rauhigkeit kann durch eine strukturierte Oberfläche, herausragende Spitzen, Wellen und dergleichen erzeugt werden.

In jeder Ausführung ist es möglich, die Scheiben zu einer soliden Einheit miteinander zu verkleben, z.B. mit PMMA-Zement, wenn erforderlich oder zweckmäßig.

Die Scheiben werden vorzugsweise aus einem kohlenstoffaserverstärkten Kunststoff (CFK) hergestellt, wobei die Verankerungsmittel je nach Ausgestaltung des Implantats aus demselben oder einem anderen Material bestehen können. Die Herstellung des gesamten Implantats aus CFK hat den Vorteil, daß das Implantat keine Streuung von Strahlen bewirkt, so daß die Wirbelsäule und das angrenzende biologische Gewebe auch nach dem Implantieren eines Wirbelkörpersersatzes mit röntgenbildgebenden Verfahren (CT, MR) untersucht werden kann.

Bekannte Wickeltechniken lassen sich zur seriennützigen Fertigung der Implantat-Elemente anwenden. Die Ringscheiben können beispielsweise mittels einer Flachmaschine, die zusätzlich mit unidirektionalen Fasern (UD) bestückt ist, hergestellt werden. Mittels eines Stabdorns, der durch das Flachzeug gezogen und mit UD-Fasern und Flachwerk umlagert wird, wird ein Faserverbundrohr in einem Arbeitsgang hergestellt, von dem dann die Ringscheiben abgeschnitten werden. Der Stabdorn ist vorzugsweise aus dem auch als Trennmittel verwendbaren PTFE (Polytetrafluorethylen). Der Stabdorn kann dabei ein Viateck als Querschnitt haben oder über die Länge Nuten und/oder Erhebungen aufweisen, wodurch im Faserverbundrohr bzw. in den Ringscheiben die für die drehsichere Verankerung erforderliche Innenmantelgeometrie direkt bei deren Herstellung gebildet wird.

Auch Wickelverfahren unter Anwendung von Fasern oder Faserlagen erlauben fertigungstechnisch einfache und für Serienfertigung geeignete Herstellverfahren. Es können einhöhlige Straben für die Einzelscheiben und die Scheibenpackungen konzipiert werden.

Die Erfindung wird anhand von in der Zeich-

nung schematisch dargestellten Ausführungsbeispielen näher erläutert. Es zeigen:

Figuren 1 und 2

ein erstes Ausführungsbeispiel,

Figuren 3 und 4

ein zweites Ausführungsbeispiel,

Figuren 5 bis 8

je ein weiteres Ausführungsbeispiel.

Die Erfindung liegt der Gedanke zugrunde, daß der Chirurg an Ort und Stelle direkt nach Kenntnis der tatsächlichen Abmessungen den Wirbelkörpersersatz zusammenstellt, ohne die Hilfe eines Prothesenlechnikers. Dazu wird ein Vorrat von Stängen unterschiedlicher Durchmesser und/oder eines Sortiments von Implantatkomponenten unterschiedlicher Durchmesser und Höhen gehalten, so daß für den jeweiligen Fall entweder eine entsprechende dicke Scheibe aus dem entsprechenden Stang herausgereinert oder die entsprechende Anzahl von Komponenten mit entsprechenden Abmessungen herausgeholt und zusammengesetzt zu werden braucht, ohne Schraubjustier- oder andere Handgriffe vornehmen zu müssen. Die Auswahl der Scheiben nach ihrer Höhe im letzten Fall kann mittels eines Rechners erfolgen.

Die Grundlage eines zusammengesetzten Implantats besteht im Aufstapeln von vorgefertigten Scheiben, wobei diese Scheiben eine runde, mehrrecksche oder unregelmäßige Außenkontur haben können. Es können volle Scheiben oder auch Ringscheiben als Komponenten verwendet werden. Es werden Scheibenätze mit unterschiedlichen Durchmessern benötigt, wobei jeder Satz eines Durchmessers mit Scheiben unterschiedlicher Höhe bestückt ist. Stahl der Durchmesser des einzusetzenden Implantats fest, so werden in dem entsprechenden Scheibenatz noch die entsprechenden Höhen ausgesucht, so daß nach dem Zusammensetzen der gewählten Scheiben sich die erforderliche Implantathöhe ergibt.

Um das Sortiment bezüglich der Scheibenhöhe möglichst klein zu halten, können beispielsweise wenige hohe Abmessungen vorgesehen werden, die mit niedrigen Scheiben, z.B. millimeterdicken Scheiben, entsprechend ergänzt werden.

In Fig. 1 ist ein Ausführungsbeispiel gezeigt, bei dem ein fertiges Implantat 10 aus drei dicken Scheiben 11, einer dünnen Scheibe 12 und zwei Endscheiben 13 bzw. 14 zusammengesetzt ist.

Wie in Fig. 2 dargestellt ist, bestehen die Scheiben 11 bis 14 aus runden Ringscheiben mit einer Innenbohrung 15 und jeweils vier regelmäßig auf die Ringscheibe verteilten Bohrungen 16. In diese Bohrungen 16 werden Verankerungselemente 17 eingebracht. Gemäß der Ausführung nach Fig. 1 sind die Elemente 17 mit ihren jeweils einem Ende 18 mit einer Scheibe 11, 13 verbunden, während sie mit dem anderen Ende 19 in die Bohrung einer näch-

porn feststellbar ist, wird mittels dieses Wertes im Rechner die Zusammensetzung der Scheibenhöhen für das Implantat errechnet, herausgesucht und zusammengesetzt oder mittels eines genau einstellbaren Werkzeugs die Scheibe vom Strang abgetrennt. Die angrenzenden Wirbelkörper werden etwas auseinandergezogen und das im Baukastensystem zusammengesetzte Implantat bzw. die Scheibe zwischengelegt. Außer dem Platzieren des Implantats sind keine weiteren Handgriffe bezüglich des Implantats notwendig. Außer der Implantathöhe variiert auch der Durchmesser des Implantats. Das Scheiben- und/oder Strangsortiment ist daher auch nach Querschnitten zu bestücken.

In Fig. 8 ist schließlich ein hohler Strang 50 unregelmäßiger Konfiguration gezeigt, der aus 1 bis 20 Flechtwerken 51 gebildet ist. Ein nicht gezeigter Dorn wird entsprechend oft durch das Ringladenauge einer Flechtmaschine gezogen und dabei mit entsprechend vielen Flechtwerken und Matrixmaterial überzogen. Mit Trennscheiben werden an Trennlinien 52 die Scheiben 53 für ein Implantat oder Implantatelement herausgeschnitten.

#### Patentansprüche

1. Implantat für die Wirbelsäule, bestehend aus mindestens einem steilen Element, dadurch gekennzeichnet, daß das Implantat aus mindestens einer Scheibe (11 bis 14, 21, 35, 45, 53) besteht, die direkt zwischen zwei angrenzenden Wirbelkörpern zwischenlagbar ist und je nach Wirbellage parallel oder zueinander im Winkel stehende Auflageflächen hat.
2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Scheibe als Ringscheibe (35, 45, 53) mit regelmäßigem oder unregelmäßigem Umfang ausgebildet ist, und daß der Innenumfang der Scheibe einen vieleckigen oder unregelmäßigen Querschnitt hat.
3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Auflageflächen der Scheibe (14, 35, 53) Rauhigkeiten, Porositäten oder andere Unebenheiten aufweisen.
4. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Auflageflächen der Scheiben (14, 35, 53) herausragende Spitzen (20) aufweisen.
5. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (45) Kanäle (46) aufweist, in die Knochenzement oder Knochenmaterial einbringbar ist.
6. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (11 bis 14, 21, 35, 45, 53) aus laserverstärktem Kunststoff besteht und im Wickelverfahren oder ausaufgerollten Fasermatten hergestellt ist.
7. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (53) aus einem Strang (32, 33 bzw. 50) geschnitten ist.
8. Implantat nach Anspruch 7, dadurch gekennzeichnet, daß der Strang (32, 33 bzw. 50) aus unidirektionalen Fasern (32) und/oder Flechtlagen (33, 51) besteht.

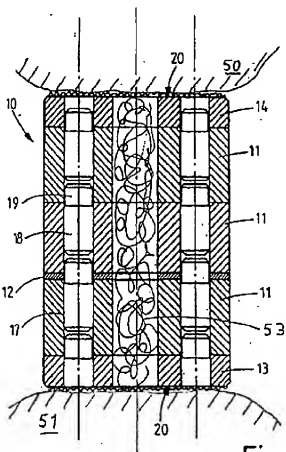


Fig. 1

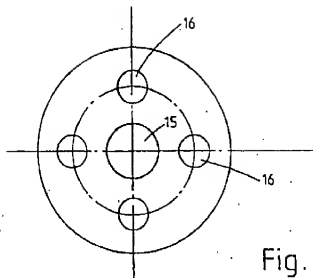


Fig. 2

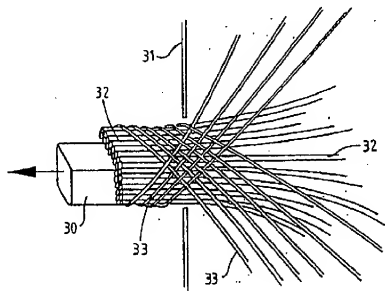


Fig. 5

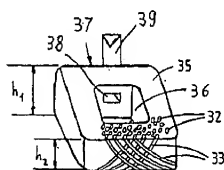


Fig. 6

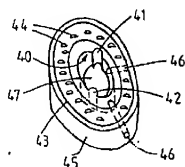


Fig. 7

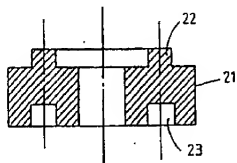


Fig. 3

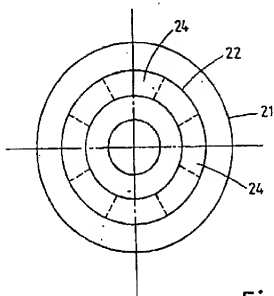


Fig. 4

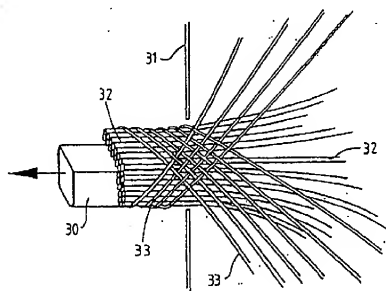


Fig. 5

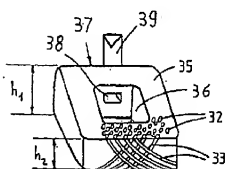


Fig. 6

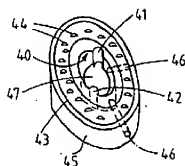


Fig. 7

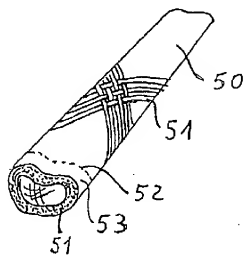


Fig. 8

Attachment A

0517030EP

PTO 2005-1131

Translated from the GERMAN

European Patent Office

EUROPEAN PATENT APPLICATION

O 517 030 A2

IPC: A61F 2/44

Application number: 92108405.9

Date of application: May 19, 2005

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Priority: June 4, 1991 DE 4118316

May 8, 1992 DE 4215137

Date the unexamined patent application, on which no grant has taken place on or before the said date, has been made available to the public by printing or a similar process: December 9, 1992 in 'Patentblatt' 92/50

Designated high contracting parties to regional patent

conventions: CH DE FR GB IT LI

Applicant: MAN Ceramics GmbH

Inventor: Wolfgang Siebels, Spitzwegstraße 17, D-8360 Deggendorf and Rudolf Ascherl, Türkenstraße 53, D-8000 Munich

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[Title in German of the object of the invention:]  
Wirbelkörperimplantat

INTRAVERTEBRAL BODY IMPLANT

The invention pertains to an intravertebral (intraspinal) body implant for vertebral (spinal) columns consisting of at least a rigid element.

Intravertebral bodies have different size along a spinal column, and vary from patient to patient. Therefore, when an

intravertebral body is substituted by an implant, it is necessary that the implant is matched to the effective size of the interval between the adjacent intravertebral bodies.

In order for an allowance to be made for this interval, implants were developed (DE 30 23 942 C3), which essentially consist of two parts, which are connected to one another by means of a threaded connection, and whose axial height can be changed by rotation, or which can be matched to the interval between the intravertebral bodies. By means of transverse bolts or other means of anchoring, the two parts are anchored in a way, which is resistant to torsional stress or prevents a rotation. Therewith, by means of a single embodiment an entire range of intervals can indeed be covered, however the adjustment in height takes relatively much time in the case of a fine thread.

An implant of the generic kind, which rectifies this imperfection, is known from the WO 90/00037, which implant is inserted solely between two vertebrae by means of a tool. However, the approximately rectangular implant is assembled out of intricate individual parts.

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is

achieved with the help of the features, cited in claim 1.

Not only is a disk easily inserted into a spinal gap but it can also be manufactured in such a way that it can very easily and dimensionally correct be matched to a certain case of application. For example, in the case of a specific application, it is thus possible that first of all the disk is cut out of a prefabricated solid or hollow strand, sterilized, or separated in sterile state with the help of a sterile grinding tool and sterile water. By using a coarse-grained grinding, respectively cutting tool, a rough surface, promoting the growth process, is imparted to the sectional areas of the implant (spinal) disk, which form the support for the intravertebral bodies.

Basically, the use of a disk of any configuration, be it of round, polygonal, irregular contour, is possible. Also, the inner contour of an annular disk can be created as occasion demands.

The contact surface of a disk, which is being used for the adjacent intravertebral bodies, is designed as structured for the promotion of the growth process, and is selected as being coarse, or running in different directions. Anchoring means in the form of projecting tips or spikes are used for the immediate securing of the prosthesis after the implantation takes place.

The disk-shaped implant is preferably made of fiber-reinforced plastic (FRP). In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists

of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.

In accordance with yet another embodiment of the invention, two or more disks are assembled, in order for an intravertebral body implant to be produced. In that case, a stock of an assortment of disks, having different height and diameter, is kept, available at hand. For the purposes of an implantation, the interval between the vertebrae is measured, and correspondingly thick, respectively high, disk of the assortment are combined together in such a way, that they have the desired vertical dimension in their entirety. The selected disks - they consist of parts of analogous shape, only having different height - are stacked one above another, in accordance with the modular principle, and are inserted as ready-made implant between the intravertebral bodies, which - to this end- are slightly pulled apart. Also, in this case, after the insertion of the implant, a regulation or adjustment of the latter inside the patient body is not required.

With the help of a computer, the disks' heights, which are to be combined, are instantaneously determined so that a minimal time input is required between the spinal interval measurement and the reception of the insertable implant. The radial anchoring, and the anchoring, preventing a rotation and resisting the torsional stress, of the assembled disks, can be mastered in a multifarious way.

In accordance with an embodiment of the invention, the disks have aligned boreholes, into which anchoring pins or studs can be inserted. In that embodiment, the disks are radially connected to one another, and also in such a way that they resist the torsional stress [i.e. possess torsional strength], and cannot rotate. Moreover, from a manufacturing engineering standpoint, the manufacturing of the disks is very easy.

Another possibility consists in that the disks are directly produced as having molded anchoring means, such as, e.g., groove and tongue, pin [stud] and boreholes.

Also, the disk packages can be designed as annular disks whereby the hollow space is filled with bone material or bone cement for the purposes of a radial anchoring of the rings. It is advantageous when the inner jacket of the annular disks is irregular, or has geometrical irregularities. Each deviation from the circular cylindrical shape is used for a torsionally resistant anchoring of the stacked disks when the hollow space of the annular disks is filled up with a hardening material. In

order for a reliable support of the implant - which is designed as a disk stack - to be achieved between adjacent intravertebral bodies, end-disks are provided, having a rough frontal side. The roughness can be generated by means of a structured area, projecting tips, undulations, and similar.

In each embodiment, it is possible to glue the disks with one another into a solid unit, e.g., with the help of PMMA\* cement, if required, or if functionally feasible. [\*Translator's note: PMMA = polymethyl methacrylate].

Preferably, the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means - according to the design of the implant - can consist of the same, or another material. The manufacturing of the entire implant of CFP has the advantage that the implant does not bring about any scattering of rays, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of all image-producing methods (CT\*, MR\*) [\*Translator's note: CT = charge-transfer (absorption band or electron-transfer band); MR = magnetic resonance).

Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ("washers") can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled

through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.

Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages (packings) can be designed.

The invention is elucidated in greater detail by means of exemplified embodiments, diagrammatically represented in the drawing, wherein

Figs. 1 and 2 show a first exemplified embodiment,

Figs. 3 and 4 show a second exemplified embodiment

Figs 5 thru 8 show another exemplified embodiment, each.

The notion that the surgeon directly assembles the spinal body substitute (replacement set) on the very spot by knowing the actual overall dimensions and without the help of a prosthesis

technician, forms the basis of the invention. To this end, a stock of strands, having different diameter and/or a supply of an assortment of spare implant components, having different diameter and height, is maintained so that for each relevant case either a corresponding thick disk needs to be separated from the relevant strand, or the relevant number of components, having relevant dimensions ought to be taken out, and assembled without threaded [screw] adjustments or other types of handling. In the last case, the selection of the disks according to their height can take place by means of a computer.

The base of an assembled implant consists in the stacking of prefabricated disks whereby these disks can have a round, polygonal or irregular outer contour. Solid disks or also annular disks can be used in their capacity as components. Disk assortment sets, having different diameters, are necessary whereby each assortment of a diameter is outfitted with disks, having different diameter. If one is absolutely certain about the diameter of the disk to be used, the corresponding heights are yet to be selected within the framework of the corresponding disk batch [assortment set] so that after the selected disks are assembled, the required implant height is thus produced.

For example, in order for the assortment with respect to the disk height to be maintained as small as possible, few high dimensions can be provided, which are correspondingly supplemented with lower disks, e.g., having a thickness of

several millimeters.

Fig. 1 shows an exemplified embodiment, in which a ready-made implant 10 is assembled out of three thicker disks 11, a thin disk 12, and two end-disks 13 and 14.

As diagrammatically represented in Fig. 2, the disks, 11 thru 14, consist of round annular disks, having an inner borehole 15, and four boreholes 16, respectively, which are equitably distributed over the annular disk. Anchoring pins (studs) 17 are introduced into these boreholes 16. In accordance with the embodiment, depicted in Fig. 1, the pins 17 are connected with one of their respective ends 18 to a disk 11, 13 while they protrude with the other end 19 into the borehole of the subsequent disk 11. In this embodiment, an end-disk 14 is designed without pin (stud). In an analogous way, the thin disks 12 have solely boreholes 16.

Self-evidently, it is also possible to produce the pins as structural components separated from the disks 11 thru 14 so that the pins are introduced into the boreholes 16 only when the assembly of an implant 10 takes place.

Instead of pins, groove-and-tongue systems can also be provided as anchoring means in each possible configuration.

Fig. 3 shows an exemplified embodiment, in which the disks 21 are provided with an annular [ring] spring 22 on one of the frontal sides whereas, on the other frontal side, they are provided with an annular groove 23, aligned with the annular

spring 22. In order for an anchoring to be also achieved in the torsional direction, spring segments 24 can be provided instead of the annular [ring] springs 22, as indicated by the dotted line in Fig. 4, which spring segments engage into corresponding grooved segments of the next disk.

In the diagrammatically represented exemplified embodiments, there were shown round disks, having a circularly symmetric distribution of the anchoring elements. It is self-evident that any asymmetric arrangement of the anchoring elements as well as of any outer contour of the disks is possible as long as the latter are in agreement with the contour of the intravertebral bodies.

From the standpoint of manufacturing engineering, annular disks or solid disks can easily be manufactured of any biologically compatible material because they are not bound to a particular shaping. The shape can even partially be matched to the manufacturing method. Manufacturing methods, which are adequate for the series-manufacturing are winding or pulling of bonded-fiber tubes, out of which the disks are sawn off, cut off, or separated, either as individual element or as elements for the disk packings [packages], described above. In the winding method, fibers or fibrous mats are used in accordance with known methods. In the braiding method, as depicted in Fig. 5, a correspondingly shaped bar-shaped mandrel 30, e.g., having a rectangular cross-section, is passed through a thread eyelet [guide] 31, and, in

doing so, it is surrounded with bundles of longitudinally directed, unidirectional (UD) fibers 32, impregnated with matrix, as well as with outer braiding fibers 32. After the solidification of the matrix, annular disks 35 are separated out of the bonded-fiber tube thus produced, whereby the mandrel is removed prior to or after the separation of the annular disks. The strand, which is designed as bonded-fiber tube, is used for the manufacturing of individual disks as well as for the manufacturing of a disk package, as depicted in Fig. 1.

When needed, individual disks 35 are separated as wedge-shaped ones (Fig. 6,  $(h_1 > h_2)$ ). In the neutral area 37, there can be provided openings 38, which are used to engage the implantation tools and fixation means, such as staples (cramp irons; clams; or clips) 39.

The hollow space 36 can be filled up with extraneous bone material, or with patient's own bone material, or with bone cement, which can also be introduced through the opening 38. When the disks are assembled, the bone cement is also used for the anchoring of the disks in the radial direction, and - due to the non-circular symmetric inner cross-section 36 - in the torsional direction as well. Instead of the rectangular inner cross-section, any other configuration - save the circular shape - can be selected, in order for a free rotational motion between the disks to be precluded.

Fig. 7 shows a shape, having a cylindrical inner jacket 40, which is outfitted with an elevation 42 for torsional anchoring.

If need arises, the disks or annular disks are provided with a starter foil 43- as shown in Fig 7 - surrounding adhesive cartridges 44. When two disks 45 for the formation of the implant are placed one above another, and axially compressed, the adhesive cartridges 44 burst open, so that the adhesive is distributed between the disks 45, and connects the disks with one another. The adhesive connection can be used as single connection or supplementarily to the aforementioned anchoring means.

In the embodiment in accordance with Fig. 7, there are shown additional boreholes 46, which are radially guided through the annular disk 45. They are used for the introduction of the bone cement or bone material into the hollow space 47.

On their free frontal end, used as the support for the spinal bones, the end-disks 13, 14 of an implant 10 have a surface 20, which is rough, structured, or provided with discrete elevations. In interaction with the adjacent intravertebral bodies 50, 51, which are pressing against the implant 10, the said elevations should guarantee the anchoring inside the spinal column, and be used as growth help. As described above, bone cement or material 53 can be pressed - if need arises - through a non-diagrammatically represented radial borehole into the inner borehole 15 up to the adjacent intravertebral body 50, 51. In the case of a single-disk implant, both sides are correspondingly

designed. A rough surface can be directly formed within the framework of the separation process from strand by using a coarse-grained cutting tool.

The implantation of an intervertebral disk substitute and/or an intravertebral fibrocartilage [intravertebral ligament; intervertebral cartilage] of this kind is not subject to any system-specific problems. If the surgical step has gone so far that the interval between the adjacent vertebral bodies can be adjusted, the assembly of the disk-heights for the implant is calculated in the computer with the help of this value, selected, and assembled, or with the help of a precisely adjustable tool, the disk is separated from the strand. The adjacent vertebral bodies are somewhat pulled apart, and the implant, respectively the disk, assembled within the framework of the modular method, is inserted. As far as the implant is concerned, no additional manipulation procedures or handling are necessary save for the placement of the implant. Besides the implant height, the diameter of the implant also varies. Hence, the disk and/or strand assortment is also to be supplied according to cross-sectional areas.

Finally, in Fig. 8, there is shown a hollow strand 50, having an irregular configuration, which hollow strand is formed out of 1 to 20 braidings 51. A mandrel, which is not diagrammatically represented, is often pulled through the annular thread eyelet of a braiding machine, and, in doing so, lined with

many braidings and matrix material, respectively. With the help of separating disks, the disks 53 for an implant or implant element, are cut out at separating lines 52.

#### Patent Claims

1. Implant for spinal columns, consisting of at least a rigid element, characterized in that the implant consists of at least a disk (11 thru 14, 21, 35, 45, 53), which can be directly inserted between two adjacent vertebral (intravertebral) bodies, and according to the spinal position has parallel contact surfaces [support surfaces] or contact surfaces, which are at an angle with respect to one another.

2. Implant as claimed in claim 1, characterized in that the disk is designed as annular disk (35, 45, 53), having regular or irregular circumference, and that the inner circumference of the disk has a polygonal or irregular cross-section.

3. Implant as claimed in claim 1 or 2, characterized in that the contact surfaces of the disks (14, 25, 53) have roughness, pore undulations, or other unevennesses.

4. Implant as claimed in claim 1, characterized in that the contact surfaces of the disks (14, 35, 53) have protruding tips or spikes (20).

5. Implant as claimed in one of the preceding claims, characterized in that the disk (45) has channels (46) into which bone cement or bone material can be introduced.

6. Implant as claimed in one of the preceding claims, characterized in that the disks (11 thru 14, 21, 35, 45, 53) consist of fiber-reinforced plastic, and are made within the framework of the winding method or of wound up [batched up] fiber mats [fiber webs].

7. Implant as claimed in one of the preceding claims, characterized in that the disk (53) is cut out of a strand (32, 33, resp. 50).

8. Implant as claimed in claim 7, characterized in that the strand [hank; rope] (32, 33 or 50) consists of unidirectional fibers (32 and/or braiding layers (31, 51)).

Translated by John M Koytcheff, M.Sc. (Engrg.);  
Postgraduate WHO Fellow (Env. Engrg.); USNWC Alumnus

The USPTO Translator (GERMAN & Germanic languages)  
US DEPARTMENT OF COMMERCE/USPTO/STIC/Translations Branch  
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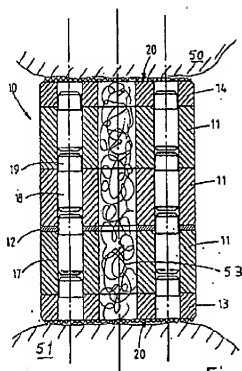


Fig. 1

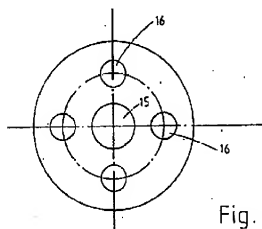


Fig. 2

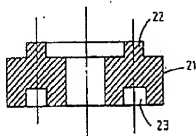


Fig.3

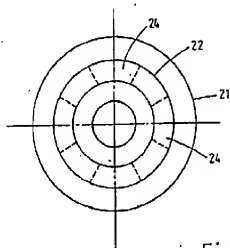


Fig.4

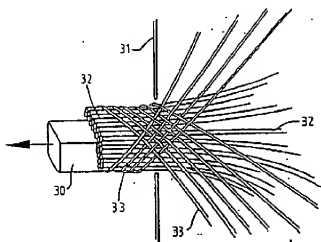


Fig. 5

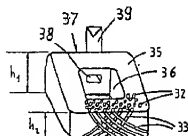


Fig. 6

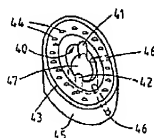


Fig. 7

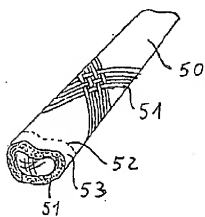


Fig. 8

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Variant(s): **also al·lo·gen·ic** (ə) /-'jē-nik/Function: *adjective*Etymology: *all-* + *-genic* (as in *syngenic*)

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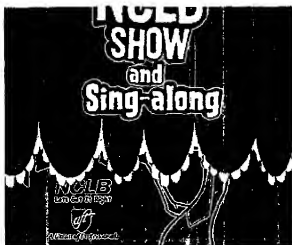
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the form of milk. The serum calcium may be raised above normal but the inorganic phosphorus of the blood, the serum phosphatase, the urinary excretion of calcium, and the calcium of the bones are all at normal levels; the condition therefore differs from the disturbances of calcium metabolism occurring in hyperparathyroidism; there is usually some degree of impairment of renal function.

**interval g.**, an asymptomatic phase between acute attacks of g.

**irregular g.**, abarritular g.

**latent g.**, masked g.; goutiness: uric acid diathesis; a condition marked by scaly eruptions of the skin, twinges in the joints, and so forth, without frank arthritis.

**lead g.**, saturnine g., masked g., latent g.  
**poor man's g.**, g. occurring in persons subject to exposure and privation and distinctly not attributable to dietetic excess.

**retrocedent g.**, the occurrence of severe gastric, cardiac, or cerebral symptoms during an attack of g., especially when the joint symptoms at the same time suddenly subside.

**saturnine g.**, g. occurring in a subject with lead poisoning.

**secondary g.**, g. resulting from increased nucleoprotein metabolism and urea acid production, in patients with diseases of the blood and bone marrow, and in lead poisoning.

**tophaceous g.**, g. in which deposits of uric acid occur in the joints and in tophi, especially of cartilaginous areas.  
**goutiness (gout-T-ness)**, Gouty diathesis; latent gout; a state in which one is prone to suffer from various scaly skin diseases, gastric disturbances, arteriosclerosis, and acute inflammations of the ocular structures which are attributable to a disturbance of metabolism, allied to gout, occurring in families in which there is a history of articular or regular gout.

**gouty (gout'g)**, relating to gout.

Gowers, Sir William R., London neurologist, 1845-1915.

See G's *column, contraction, disease, syndrome, tract*.

**Goyrand's injury**, See under injury.

**GPT**, Abbreviation for glutamic pyruvic transaminase, which is now known as alanine aminotransferase.

**gr**, Abbreviation for grain, a measure of weight.

**Grasf** (grash), Reijner de, Dutch physiologist and histologist, 1641-1673. See *Grasfian follicle*.

**gracilis** (grash'lis) [L.] [NA]. Slender; denoting a thin or slender structure.

**Gradenigo** (grah-den-e'go), Giuseppe, Italian physician, 1859-1926. See G's *syndrome*.

**gradient**, Rate of change of temperature, pressure, or other variable as a function of distance.

**atrioventricular g.**, the diastolic pressure difference between the atrium and ventricle.

**concentration g.**, density g.; a solution in which the concentration of a solute increases in a continuous fashion from top to bottom, or end to end, of a container (e.g., the centrifuge tube in density gradient centrifugation).

**density g.**, concentration g.; see also density g. centrifugation.

**electrochemical g.**, a measure of the tendency of an ion to move passively from one point to another, taking into consideration the differences in its concentration and in the electrical potentials between the two points; commonly expressed as the additional voltage needed to achieve equilibrium.

**mitral g.**, the diastolic pressure differences between the left atrium and left ventricle.

**systolic g.**, the difference in pressure during systole between the communicating cardiovascular chambers, e.g., between the left ventricle and left atrium in mitral insufficiency.

**ventricular g.**, the algebraic sum of (i.e., the net electrical difference between) the area enclosed within the QRS complex and that within the T wave in the electrocardiogram.

**graduate** (Mediev. L. *graduatus*, fr. L. *gradus*, step). A vessel, usually of glass, suitably marked, used for measuring the volume of liquids.

**graduated**, Marked by lines or in other ways to denote quantity, degrees, percentages, etc.; applied to a thermometer, barometer, etc.

**Graefe** (gra'feh), Albrecht von, German ophthalmologist, 1828-1870. See G's *disease, knife, operation, sign, pseudo-G, sign, G's spots, test*.

**Graefenberg**, Ernst, German gynecologist in America, \*1881. See G, *ring*.

**graft** [A.S. *graf*], 1. Anything inserted into something else so as to become an integral part of the latter; specifically, a bit of epidermis, strip of skin, piece of bone, tooth, etc., inserted into a part in order to supply a defect.

2. The performance of a grafting procedure.

**accedion g.**, a g. which, by means of multiple slits, can be stretched to cover a large area.

**allogeneic g.**, homograft; other than isogenic.

**anastomosed g.**, one in which circulation is established by surgical anastomoses of blood vessels.

**animal g.**, zooplasmic g.

**autodermic g.**, a skin g. from one part of the body to another.

**autogenous bone g.**, a bone g. from one part of the body to another.

**autologous g.**, autograft.

**autoplasmic g.**, autograft.

**Blair-Browne g.**, split-thickness g.

**Braun g.**, full-thickness g.

**Braun-Wangensteen g.**, g's of skin taken from large g.

**hepatoepiastic g.**, transplantation of tissue from an embryo or newborn to the adult.

**cable g.**, a multiple strand nerve g. arranged as a pathway for regeneration of axons.

**chessboard g's.**, postage stamp g's.

**chionolantonic g.**, transplanting of living material to the chionolantonic membrane of the embryonic chick.

**cutis g.**, g. of true skin, from which epidermis and subcutaneous tissue have been separated, used in plastic surgery in place of fascia.

**Davis g's.**, small, deep skin g's.

**delayed g.**, one postponed until after elimination of infection and formation of a bed of healthy granulation tissue.

**dermoepidermic g.**, see Thiersch's *method*.

**Douglas g.**, sieve g.

**fascia g.**, g. of fibrous tissue, usually the fascia lata.

**fat g.**, one used to fill a cavity or depression.

**filler g.**, a g. used for the filling of defects, e.g., filling a cyst with bone chips.

**free g.**, a g. separated from its normal attachments.

**full-thickness g.**, Braun g.; a g. of full thickness of skin and subcutaneous tissue.

**heterodermic g.**, a g. of skin from one person to another.

**heterologous g.**, heterograft.

**heteroplastic g.**, heterograft.

**heterospecific g.**, heterograft.

**heterotopic g.**, transplantation of a tissue or organ into a position it normally does not occupy.

**homologous g.**, homograft.

**homoplastic g.**, homograft.

**hyperplastic g.**, one in active proliferation.

**implantation g.**, one in which small sections of skin are placed into granulation tissue.

**infused g.**, transplantation by injection of a suspension of cells.

**interspecific g.**, heterograft.

**isogenic g.**, isograft.

**isologous g.**, isograft.

**isoplasmic g.**, isograft.

**jump g.**, a pedicle g. transferred from one position to

**Kiel g.**, denatured calf bone used to fill defects or restore facial contour; often used for chin and nasal augmentation.

**Krause's g.**, Krause's *method*.

**mesh g.**, thick-split g. of skin which has been incised in several places to allow covering a larger area and to prevent accumulation of serum beneath the g.

**mucosal g.**, a split-thickness g. involving the mucosa.

**nerve g.**, the insertion of nerve substance to fill a gap between the divided ends of a nerve; the grafted tissue acts as a bridge and does not form part of the new tissue.

**Oliver's g.**, see Thiersch's *method*.

## **EXHIBIT 21**

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:  
Bianchi, John R., *et al.*  
Serial No.: 09/782,594  
Filed: February 12, 2001  
For: "Assembled Implant"  
Group Art Unit: 3738  
Examiner: Paul B. Prebilic

CERTIFICATE OF ELECTRONIC FILING

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August 25, 2006



Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Mail Stop AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of 02/27/06 (hereinafter "the Official Action"), rejecting all claims (claims 26-34, 61 and 62) and for which a response was due 05/27/06, now extended three (3) months to 08/28/06 (08/27/06 being a Sunday), the Applicants respond as follows:

Amendments to the Claims:  
Remarks:

Pages 2-4  
Pages 5-22

## Amendments to the Claims:

Please substitute the listing of the claims as provided below for any prior listings:

Claims 1-25 (Cancelled)

26. (Currently amended) An assembled bone graft, said assembled bone graft assembled outside the body and suitable for implantation into a human patient, said assembled bone graft comprising: a plurality of machined allograft bone portions layered to form a graft unit, and biocompatible pins traversing said graft unit for holding said graft unit together as an assembled bone graft, said assembled bone graft being suitable for implantation into a human patient and does not comprise an adhesive.

27. (Currently amended) An assembled bone graft suitable for implantation in a human patient comprising:

two distinct bone portions of cortical bone, and biocompatible pins, wherein said two distinct bone portions are machined allograft bone portions processed to be suitable for implantation in a human patient, said biocompatible pins are of appropriate diameter and press fitted into machined holes in said two bone portions to hold together said two bone portions to form said an assembled bone graft suitable for implantation in humans.

28. (Currently amended) An assembled bone graft suitable for implantation in a human patient comprising two or more ~~connected~~, distinct, bone portions of machined allograft bone ~~forming a graft unit~~, and pins comprising cortical bone ("cortical bone pins"), said two or more ~~connected~~, distinct, bone portions having holes therein for receiving said cortical bone pins, said cortical bone pins keeping said two or more ~~connected~~, distinct, bone portions aligned and connected to form an said assembled bone graft free of an adhesive and suitable for implantation in a human ~~humans~~.

29. (Currently amended) The assembled bone graft of claim 28 where there are two ~~connected~~, distinct, bone portions of machined allograft bone.

30. (Currently amended) The assembled bone graft of claim 28, wherein said two or more ~~connected~~, distinct, bone portions are selected from the group consisting of: cortical bone and cancellous bone.

31. (Currently amended) An assembled bone graft suitable for implantation in a human patient, comprising:

a first machined bone portion having holes therein;

a second machined bone portion having holes therein aligned with the holes in said first bone portion, said first bone portion and said second bone portion being allograft bone suitable for implantation into a human patient; and

cortical bone pins press-fitted in said holes for holding said first bone portion in juxtaposition to said second bone portion and forming a said assembled bone graft suitable for implantation into a human patient.

32. (Currently amended) An assembled bone graft suitable for implantation in a human patient, comprising:

a first machined cortical bone portion having a hole therein;

a second machined cortical bone portion having a hole therein, said hole in said second machined cortical bone portion aligning with said hole in said first machined cortical bone portion, said first machined cortical bone portion and said second machined cortical bone portion being allograft bone suitable for implantation into a human patient;

a cortical bone pin press-fitted in the hole between said first cortical bone portion and said second cortical bone portion to form said assembled bone graft suitable for implantation into a human patient.

33. (Currently amended) An assembled bone graft suitable for implantation into a human patient, comprising:

a first machined cortical bone portion having holes therein;

a second machined cortical bone portion having holes therein aligned with the holes in said first machined bone portion, said first machined cortical bone portion and said second machined cortical bone portion being allograft bone suitable for implantation into a human patient; and

cortical bone pins press-fitted in said holes for holding said first machined cortical bone portion in stacked juxtaposition to said second machined cortical bone portion and forming, ~~without an adhesive, without an adhesive~~ said assembled bone graft suitable for implantation into a human patient.

34. (Currently amended) An assembled bone graft suitable for implantation into a human patient, comprising:

a first machined bone portion;

a second machined bone portion ~~provided on~~ contacting said first machined bone portion to form a graft unit, said first machined bone portion and said second machined bone portion being allograft bone suitable for implantation into a human patient; and

biocompatible pins inserted into said first machined bone portion and said second machined bone portion for holding together said graft unit to form said assembled bone graft suitable for implantation into a human patient.

35-60. (Cancelled)

61. (Previously presented) The assembled implant of claim 31 wherein said cortical bone pins are four cortical bone pins, said cortical bone pins being made from cortical bone.

62. (Previously presented) The assembled implant of claim 33 wherein said cortical bone pins are four cortical bone pins, said cortical bone pins being made from cortical bone.

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## REMARKS

The amendments to the claims do not add new matter. Claim 26 has been amended to recite “said assembled bone graft assembled outside the body and suitable for implantation into a human patient.” The latter portion of the above phrase “suitable for implantation into a human patient” has been moved from the end of claim 26 to the beginning. Hence, it does not add new matter. The first portion of the phrase “said assembled bone graft assembled outside the body” is actually inherent as a result of the latter phrase that the “assembled graft” pre-exist outside the body to be “suitable for implantation into the body.” Further support for the “assembled graft” existing in assembled form outside the body is found throughout the specification, including the description of each of Figures 2-22, at page 3, line 27 to page 4, line 6, referring to the depicted “assembled implant” according to this invention.

Separately, each of claims 26-34 has been amended to reflect that the allograft bone portions are “machined” to have a predetermined shape. Support for the bone portions of the assembled allograft being “machined” is found throughout the specification, including at page 5, lines 25-27 (“The assembled pieces may first be machined to desired dimensions and shapes, prior to assembly, the assembled implant may be machined, or both.”).

For all these reasons, the amendments to the claims do not add new matter.

### Summary of the Bases for Objection /Rejection

Claims 26-34 and 60-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154.

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis).

Claims 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis).

Claims 26, 27, 31-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis).

Claims 26-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates).

Each of these five (5) bases for rejection is addressed in Sections I-V, respectively, which follow.

## **I. Obviousness Type Double Patenting**

Claims 26-34 and 61-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154. The Applicants will address this issue at such time as claims are allowed in the present application. Applicants are considering cancelling claim 79 in the copending application.

## **II. 35 U.S.C. § 102(b) over U.S. Pat. 5,147,367 (Ellis)**

### **A. Ellis does not teach a “machined” portion of bone**

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). Each of claims 26-34 has been amended to recite as an element that the bone portions of the assembled bone graft are “machined” to have a predetermined shape. Ellis simply discloses reattaching a single fractured piece of bone to the “adjacent underlying bone mass” from which it originally fractured. [See Ellis at col. 4, lines 16-18 (“FIG. 2a depicts a femur 20 which contains a fractured condyle 201 and an **adjacent underlying bone mass 202**.”); emphasis added in bold.] Because the bone fragment of Ellis fractured, it is already the perfect shape to fit the location from whence it came. At no time does Ellis disclose machining the fractured bone piece into another shape. For this reason, claims 26-34 would not be anticipated by Ellis.

**B. Ellis does not disclose an assembled bone graft that exists in assembled form outside the body**

Each of claims 26-34 includes as a limitation that the **“assembled bone graft”** be **“assembled outside the body and suitable for implantation into a human patient”** (claim 26) or that the **“assembled bone graft”** be **“suitable for implantation into a human patient”** (claims 27-34). In Ellis, only a single bone portion is shown as a fractured fragment. It may be argued that the single fractured fragment exists as a part of an assembled bone (but not “graft”) inside the body. However, that single bone fragment portion never exists in “assembled” form outside the body as an **“assembled bone graft”** that is **“suitable (in assembled form) for implantation into a human patient.”** For this reason also, claims 26-34 would not be anticipated by Ellis.

In addition, each of claims 26-34 recites as an element that the **“assembled bone implant”** that is **“suitable for implantation in a human patient”** include **two or more** **“bone portions.”** In contrast, Ellis only discloses a **single** bone fragment that is re-affixed to the underlying position from where it fractured. The single fractured piece of bone of Ellis is never assembled to another portion of bone outside the body so as to be suitable for implantation into a human patient. Moreover, as discussed in Section (I)(A) *supra*, the fragment of Ellis is not “machined” to have some predetermined shape. Hence, Ellis never discloses the existence outside the body of an **“implantable bone graft”** comprising a **machined first bone portion** and a **machined second bone portion**. For these reasons also, claims 26-34 would not be anticipated by Ellis.

**C. Ellis does not teach or suggest a “graft” as the term is understood in the art**

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). Claims 26-34 are directed to an **“assembled bone graft. . . .”** According to the Patent Office, **“Ellis anticipates the claim language where the bone pieces or bone portions of the same patient are grafted back onto the bones they were separated from to form a graft. . . .”** [Official Action at pages 3-4, citing Ellis at the figures, the abstract, and column 5, lines 12-56; emphasis added in bold.] The word

"graft" **never** appears in Ellis and it is for a good reason. As a person skilled in the art, Ellis knew that he was not "grafting" when he re-attached a fragment of bone to the **same** site from which it fractured. In the bolded language above, the Patent Office acknowledges that Ellis discloses binding the bone back to the location that it was "**separated from,**" i.e., the **same** location. Also in FIGs 2a-2d and FIGs. 3 and 4 of Ellis, Ellis discloses binding a single "bone fragment" to the **same** (underlying) "bone mass" from which it separated. [See Ellis at col. 4, lines 16-18 ("FIG. 2a depicts a femur 20 which contains a fractured condyle 201 and an **adjacent underlying bone mass 202.**"); emphasis added in bold.] As support for the Patent Office's position that the separated "bone fragment" of Ellis is a "graft," the Patent Office cites to Stedman's Medical Dictionary, 23<sup>rd</sup> Edition (1976) at page 599 for the definition of "graft" as "anything **inserted** into something else so as to become an integral part of the latter." [Official Action at page 4; emphasis added in bold.]

However, if Ellis is actually disclosing a "bone graft," as alleged by the Patent Office, and the source of bone is clearly from the same patient (autogenous), then the more relevant definition in the PTO's own authoritative reference (i.e., Stedman's Medical Dictionary, the same page is "autogenous bone graft." Under this definition, such a "bone graft" comes from "**one part of the body to another**":

autogeneous bone graft- a bone g[raft] from one part of the body to another.

[Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, (1976) at p. 599; emphasis added in bold.

Because the bone in Ellis is from the same patient, it is clearly "autogenous." However, the bone repair described in Ellis, does not satisfy the remaining portion of the definition of "bone graft" because the bone is not "from one part of the body to another." One skilled in the art recognizes that the graft from one part of the body is a "shaped" piece that is shaped to fit another. Because the bone in Ellis has its natural shape and is fixed to its original location, it is a repair and not a "bone graft" even as that term is defined in the Patent Office's own reference. For this reason also, Ellis is not anticipatory of claims 26-34.

### III. 35 U.S.C. § 103(a) over U.S. Pat. 5,147,367 (Ellis)

Claims 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, “Ellis discloses using ‘any number of pins or screws’ to secure the bone portions together but not the use of ‘four’ pins as claimed.” [Official Action at page 5.] The Patent Office then contends that “the use of ‘four’ pins would have been considered *prima facie* obvious to an ordinary artisan. [Official Action at page 4.] The Applicants respectfully submit that the cited reference fails to make a *prima facie* case of obviousness against the present invention.

As an initial matter, claims 61 and 62 are ultimately dependent upon claims 31 and 33, respectively. As dependent claims, claims 61 and 62 incorporate all of the limitations of the base claim and any intervening claims. Independent claims 31 and 32 include as an element “machined” bone portions of “allograft” bone “suitable for implantation into humans.” [See Section II(A) *supra*.] The single bone fragment of Ellis is not “machined.” It is used in its natural shape so as to fit the point of fracture like a piece of a puzzle. For this reason, claims 61-62 would not have been obvious over Ellis.

Separately, in Ellis, the fragment of bone that is re-attached to the site from which it fractured is “living” bone. One skilled in the art recognizes that the “living” (autograft) bone of Ellis is structurally different than the “allograft” bone of the Applicants’ invention, which is processed to be “non-living” by removal of all foreign antigens and living cells, which could evoke an immune response, to render the “assembled bone graft” “suitable for implantation into a human patient.” [See Exhibit D: Spine School at page 2, para.2.] Thus, even if Ellis could be construed as suggesting the use of 4 pins, Ellis would not have rendered obvious the Applicants’ invention as a whole because Ellis never taught or suggested the use of dead and processed bone tissue.

Finally, Ellis never teaches or suggests a graft that is “assembled” outside the body so as to be an “assembled bone graft suitable for implantation into a human patient.” [See Section II(B) *supra*.] Rather in Ellis, the only “assembled bone” exists exclusively as part of the body because the main bone mass to which a fragment is re-

attached is part of the living human body. For any one of these reasons, claims 61-62 would not have been obvious over the disclosure in Ellis.

#### IV. 35 U.S.C. § 103(a) over U.S. Pat. 5,716,358 (Ochoa) in view of Ellis

Claims 26-27, 31-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, "Ochoa discloses bone portions or pieces **grafted back onto the bones they were separated from . . .**" [Official Action at page 5, citing Ochoa at Figures 4 and 5, and column 6, line 57 to col. 8, line 47; emphasis added in bold.] In the bolded language above, the Patent Office acknowledges that Ochoa discloses binding the bone back to its **original** location (*i.e.*, the location that it was "separated from"). In the same sentence, the Patent Office admits that Ochoa "fails to clearly disclose the use of a plurality of pins as now claimed." [Official Action at page 5; emphasis added in bold.] To make up for this admitted deficiency, the Patent Office cites to Ellis for allegedly teaching that "it was well known to use a plurality of pins to attach bone pieces together." [Official Action at page 5; emphasis added in bold.] The Applicants respectfully submit that the cited combination fails to make a *prima facie* case of obviousness against the presently claimed invention.

In particular, each of independent claims 26-27, 31-34 and 61-62 has been amended to recite that the two or more bone portions therein are "machined" portions of allograft bone. In Ellis and Ochoa, the bone fragment and fragments, respectively, retain their natural shape at the interface of the fracture(s), respectively. They are not machined to a predetermined shape. Because, the combination of Ochoa and Ellis fails to teach any "machined" bone portions, claims 26-27, 31-34 and 61-62 would not have been obvious over Ochoa in view of Ellis. Separately, it should be pointed out for the record that the bones in Ochoa are living, although for purposes of clarity, they shown separate from the muscle, tendons, veins and arteries. It is the fixation device of Ochoa which is implantable. See Claim 1 of Ochoa.

Claims 26-27, 31-34 and 61-62 also include the limitation that the assembled bone graft, which is comprised of two or more portions of allograft bone, be "suitable for implantation in a human patient." To be suitable for implantation in a human patient, the "allograft" bone (which is "genetically distinct" as admitted by the Patent Office<sup>1</sup>) is processed to remove all living cells, such that it is **non-living**. [Exhibit D: Spine School at page 2, Para 2.] In addition, it has been processed to remove fat and proteins, the latter of which would be recognized as foreign and rejected by the graft recipient. Unless "allograft" bone is non-living and has been processed to remove foreign antigens (i.e., proteins and cells) it would not be suitable for use in humans. In marked contrast, both Ochoa and Ellis, as acknowledged by the Patent Office, teach how to re-attach a fractured fragment of **living** bone back to its original **living** bone mass. Neither Ochoa nor Ellis teaches or suggest the use of "allograft" bone that has been processed (to death) to be "suitable for implantation in a human patient." For any and all of these reasons, the combination of Ochoa and Ellis would fail to make a *prima facie* case of obviousness against claims 26-27 and 31-34 or their dependents (claims 61 and 62).

Separately, each of the Applicants' claims is directed to an "**assembled** bone graft" that is "suitable for implantation into a human patient." By use of the adjective "assembled," the "assembled bone graft" that is "suitable for implantation in a human patient," must exist in "assembled" form **outside** the body of a human patient to be "suitable for implanting into a human patient." In contrast, in both Ochoa and Ellis, the "assembled" bone species only exists in "assembled" form **inside** and as part of the living body of the human patient because it is assembled *in vivo*. Hence, at no time does Ochoa or Ellis teach or suggest an "assembled bone graft" (that exists in assembled form outside the body) so as to be "suitable for implantation into a human patient." For this reason also, the combination of Ochoa and Ellis would fail to make a *prima facie* case of obviousness against claims 26-27 and 31-34 or their dependents (claims 61 and 62).

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<sup>1</sup> "'Allograft' is a homograft (i.e., from the same species) that is allogeneic (i.e., genetically distinct) to the recipient." [Official Action at page 4, lines 4-5].

V. 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates)

Claims 26-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates). According to the Patent Office, Siebels discloses "an assembled bone implant made by assembling separate bone implant pieces together by aligning bores of adjacent pieces;" and introducing "pins into the aligned bones to hold the implant pieces together." [Official Action at page 6.] The Patent Office admits that "Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic . . . or carbon-fiber reinforced plastic. . . ." [Official Action at page 6.] To make up for this deficiency, the Patent Office cites to Coates, alleging that Coates "teaches that it was well known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61." [Official Action at page 6.] The Patent Office then concludes that it would have been obvious to make the discs and pins of Siebels implant out of cortical bone for the same reasons the [sic] Coates teaches doing the same. The Applicants respectfully disagree.

As acknowledged by the Patent Office, Siebels acknowledges that Siebels "mentions a preference for fiber-reinforced plastic . . . or carbon-fiber reinforced plastic. . . ." [Official Action at page 6.] The mentioned preference for plastic is over metal because "the implant does not bring about any scattering of rays, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of image-producing methods (CT\*, MR\*) [Translator's note: CT = charge transfer (absorption band of electron-transfer band); MR = magnetic resonance]." [Translation at page 6.] One skilled in the art recognizes that the referenced "scattering of rays" refers to both X-rays and magnetic field lines which would be influenced by the presence of a metal implant. Notwithstanding the PTO's translation of CT as "charge transfer," one skilled in the art recognizes that this translation is erroneous and that CT refers to the x-ray technique of "computed tomography" which would be

obstructed by a metal implant. Thus, Siebels teaches a preference for reinforced plastic over metal implants.

Coates teaches a preference for cortical bone implants over metal implants. In particular, Coates states “bone as an implant also allows excellent post-operative imaging because it **does not cause scattering like metallic implants** on CT or MRE imaging.” [Coates at col. 2, lines 63-65; emphasis added in bold.] However, neither Siebels nor Coates, alone or in combination, teaches or suggests a preference for the bone of Coates over the reinforced plastic of Siebels. Even assuming for the sake of argument that it would have been “obvious to try”, “obvious to try” is not the test for obviousness. *See In re Goodwin*, 198 USPQ 1 (CCPA 1978) (“However, this court has consistently refused to recognize obvious to try rejections. As we have said many times, obvious to try is not the standard of 35 USC 103. . .”).

**A. The Combination of Siebels and Coates Fails to Provide a “Suggestion to Combine” or a Reasonable Expectation of Success**

In order for an invention to be obvious, “Both the suggestion and the expectation of success must be founded in the prior art, not in applicant’s disclosure.” *Amgen v. Chugai*, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, Siebels discloses that it was an object of their invention to make an implant that can “**easily be manufactured for a multiplicity of overall dimensions:**”

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured for a multiplicity of overall dimensions**, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.

[English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

To achieve the “case” of manufacturing, Siebels relies upon cutting discs out of “prefabricated solid or hollow strand.” [English Translation of Siebels at page 3, line 7.]

Specifically, Siebels discloses that this mode of manufacturing, comprising cutting appropriately sized strands made of “fiber reinforced plastic” provides for “manufacturing” in an “**extraordinarily easy way**”:

The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be **manufactured** in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity and strength** to the implant.

[English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

Thus, the heart of Siebel’s invention is a prefabricated template that can be cut into directly useable slices to produce an implant “in an **extraordinarily easy way**.” By use of the adjective “extraordinary,” Siebels meant to convey that the disclosed process of manufacturing plastic implants was not just “easy” but “**extraordinarily easy**.”

In addition, the above quote from Siebels teaches that “**fiber orientation**” is important because it “imparts an **optimal rigidity**.” The word “**optimal**” is a superlative and means “most favorable or desirable; best; optimum.” [Exhibit G: Webster’s New World Dictionary, Second College Edition, Ed. Guralnik, Prentice Hall Press, 1986 at page 999; emphasis added in bold.] Thus, **fiber orientation** is a necessary element in the material used by Siebels to “impart **optimal rigidity**.”

In contrast to the “extraordinarily easy” method of manufacturing disclosed in Siebels (that provides for an implant having “optimal rigidity”), Coates discloses that “developing an implant having the biomechanical properties of metal and the **biological properties of bone** without the **disadvantages of either** has been **extremely difficult or impossible**.” [Coates at col. 3, lines 35-39.] By this statement, Coates teaches that as of its filing date (October 1995), cortical bone was not a “traditional orthopedic implant

material” for spinal implants. Rather, it was considered “**extremely difficult or impossible**” to provide an implant that had the benefits of both bone and metal without their undesired properties. The words “extremely difficult or impossible” are superlatives related to difficulty or impossibility. Given this “**extremely difficult or impossible**” setting of developing an implant from cortical bone, one skilled in the art would not have been motivated to substitute the “**extremely difficult or impossible**” cortical bone of Coates for the “**extraordinarily easy**” fiber reinforced plastic of Siebels. Moreover, given the teaching in Coates of the “**extreme difficulty or impossibility**” of developing a **single piece** implant from cortical bone, one skilled in the art would have been even **less motivated** to build an implant assembled from little pieces of cortical bone held together with pins, than from the “**extraordinarily easy**” fiber reinforced plastic of Siebels. Moreover, given Coates teaching of the “**extreme difficulty**” in making even a single piece implant from cortical bone, there would **not** have been the requisite reasonable expectation of success that the Applicants’ would have been able to make implants assembled from little pieces of cortical bone. See *Amgen v. Chugai*, 18 USPQ2d at 1022. For these reasons, claims 26-34 and 61-62 would not have been obvious under 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates).

#### **B. The Cited Art Teaches Away from Combining Siebel with Coates**

“A prior art reference may be considered to teach away when ‘a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant.’” See *Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998); emphasis added in bold. In the present case, one skilled in the art, upon reading Siebels “extraordinarily easy” method for producing an implant having “optimal rigidity” due to the fiber orientation would have been led in a direction **divergent** from the “**extremely difficult or impossible**” path of making a single piece implant from cortical bone as disclosed in Coates. Because Siebels led in a divergent direction from the path taken in Coates, Siebels taught away from Coates as a matter of law. *Monarch Knitting*, 45 USPQ2d at 1984. It is “error to find obviousness where references ‘diverge

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from and teach away from the invention at hand.” *In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) *citing Gore v. Garlock*, 220 USPQ 303, 311 (Fed. Cir. 1983). For this reason also, the combination of Siebels and Coates would have failed to make a prima facie case of obviousness at the time the Applicants’ invention was filed.

**C. The Prior Art As A Whole Fails to Teach a Plurality of Advantages for the Cortical Bone Implant of Coates**

The Patent Office contends that “Coates teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties *in vivo*.” [Official Action at page 6.] The Applicants respectfully disagree. Coates teaches that there were numerous difficulties associated with autograft and allograft implants made from cortical bone, including trauma to other sites, sizing, slippage, displacement and permanent neural injury to the patient:

**Unfortunately, the use of bone grafts presents several disadvantages. Autograft is available in only limited quantities. The additional surgery also increases the risk of infection and blood loss and may reduce structural integrity at the donor site. Furthermore, some patients complain that the graft harvesting surgery causes more short-term and long-term pain than the fusion surgery.**

**Both allograft and autograft present additional difficulties. Graft alone may not provide the stability required to withstand spinal loads. Internal fixation can address this problem but presents its own disadvantages such as the need for more complex surgery as well as the disadvantages of metal fixation devices. Also, the surgeon is often required to repeatedly trim the graft material to obtain the correct size to fill and stabilize the disc space. This trial and error approach increases the length of time required for surgery. Furthermore, the graft material usually has a smooth surface which does not provide a good friction fit between the adjacent vertebrae. Migration and expulsion of the graft may cause neural and vascular injury, as well as collapse of the disc space. Even where such slippage does not occur, micromotion at the**

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graft/fusion-site interface **may disrupt the healing process** that is required for fusion.

[Coates at col. 3, lines 10-32; emphasis added in bold.]

Thus, Coates does teach that there are difficulties associated with implants made from cortical bone which are not described for implants made from fiber reinforced polymer of Siebels.

One of the properties to be considered is the ease of manufacturing the implant. The ease of manufacturing was discussed both in Siebels and in Coates. Siebels teaches that implants made from fiber-reinforced polymer can **“easily be manufactured for a multiplicity of overall dimensions [sizes]”**:

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured for a multiplicity of overall dimensions**, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.

[English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

Siebels discloses that his implants can be made in an **“extraordinarily easy way”** and provide **“optimum rigidity”** and **“strength”** to the implant:

Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity** and **strength** to the implant.

[English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

In contrast to the **“extraordinarily easy way”** of Siebels, Coates teaches that “developing an implant having the biomechanical properties of metal and the **biological properties of bone** without the **disadvantages of either** has been **extremely difficult or impossible.”**

[Coates at col. 3, lines 35-39.] Thus, the material and method used to produce the device of Siebels has at least one major advantage ("**easily be manufactured for a multiplicity of overall dimensions**") not found in the implant of Coates.

The fiber-reinforced plastic and the carbon-reinforced plastic of Siebels is the same fiber reinforced plastic and the carbon reinforced plastic disclosed in U.S. Pat. 5,192,327 (Brantigan) which is attached as Exhibit H and cited in a cofiled IDS. When Coates addressed its advantages over the prior art, the advantages were in relation to "metal" implants, not the fiber-reinforced implants of Siebels or Brantigan:

developing an implant having the biomechanical properties of **metal** and the biological properties of bone without the **disadvantages of either** has been **extremely difficult or impossible**.

[Coates at col. 3, lines 35-39.]

Coates fails to address or overcome the stated manufacturing advantages associated with the fiber reinforced plastic of Siebels, so as to motivate one skilled in the art to disregard the ease of manufacturing advantages associated with Siebels. In fact, Siebels states that his preferred embodiment imparts "**optimal rigidity**." [English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.] Brantigan also teaches that the fiber- and carbon-reinforced plastic polymers, such as "Peck," are "radiolucent," unlike metal. [Brantigan at col. 3, lines 9-18.] Coates never addressed or showed superiority over the "optimal rigidity" in the implants of Siebel. Coates also never addressed or established a manufacturing advantage over the "**extraordinarily easy way**" in which the implants of Siebels are manufactured. Rather Coates taught the opposite, stating that even Coates large single piece cortical bone implants were "**extremely difficult or impossible**" to manufacture.

Both Coates and Siebels teach that their implants have the same advantage of being radiolucent versus the radio opaqueness of the prior art metal implants. Siebels also teaches that its **preferred embodiment**, which is a fiber (e.g., graphite) reinforced plastic (FRP), has advantages over metals, which are associated with the disadvantageous stress-shielding and radio [X-ray]-opaqueness:

Preferably the disks are made of a carbon-fiber reinforced plastic (CFP) . . . . The manufacturing of the entire implant of **CFP has the advantage** [over metal] **that the implant does not bring about the scattering of rays**, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of all **image-producing methods (CT\*, MR\*)**.

[English Translation of Siebels at p. 6, lines 10-18; emphasis added in bold.]

Like Coates, Brantigan teaches at col. 3, lines 9-12 that “The **implants are preferably made of radiolucent material** such as **carbon fiber reinforced polymers** known commercially as ‘Peek’ (polyetheretherketone) or ‘ultrapeek’ (polyether ketone, ether ketone, ketone).” Thus, the implants of Coates and Brantigan each have the same advantage of being radiolucent. Thus, the radiolucence of cortical bone of Coates offers no motivation to substitute over the already radiolucent polymers of Siebels.

Further, Coates’ arguments at col. 2, lines 54-65 regarding the stress shielding caused by the stiffness of titanium alloys (114Gpa) and 316L stainless steel (193Gpa) versus cortical bone (about 17Gpa) do not apply to the carbon fiber reinforced PEEK (17.8 Gpa), or similar carbon fiber reinforced polyetherketoneetherketoneketone (PEKEKEKK) (6.9-29.4 Gpa) or carbon fiber reinforced polycarbonate (4.1-21.4 Gpa) as disclosed in Brantigan at col. 3, lines 9-13. [See Exhibit I : from [www.matweb.com](http://www.matweb.com) at page 2, line 10 “Flexural modulus”.] These fiber-reinforced polymers have a stiffness (e.g. 17.8 Gpa) that is analogous to the stiffness of cortical bone (about 17 Gpa) and substantially less than the stiffness (114-193 Gpa) of the recited metals. [These arguments apply with equal force regarding the carbon fiber reinforced plastic of Siebels in Section III supra.] Thus, the fiber-reinforced plastics of Brantigan (and Coates) do not have the disadvantage of “stress shielding” that is associated with metals. Moreover, they have the same flexibility modulus as cortical bone. Thus, the advantageous property, lack of stress shielding, of cortical bone over metal is not an advantageous property over the fiber-reinforced polymers of Siebels. In fact, Siebels teaches that the fiber-reinforced polymers of the implants of his invention impart “**optimal rigidity and strength**”:

The disk-shaped implant is **preferably made of fiber-reinforced plastic [FRP]**. In accordance with a **preferred embodiment of the invention**, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity and strength** to the implant.

[English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

By the word “**optimal**”, Siebels means that his materials are the best for strength (due to fiber orientation) and **rigidity**. Coates does not address this teaching in Siebels. Thus, Siebels teaches that the fiber-reinforced polymers of his invention have at least two advantages relative to the single piece cortical bone implants of Coates: “manufactured in an **extraordinarily easy way . . . optimal rigidity and strength** to the implant.”

While the implant of Coates, which is made of Cortical bone, is stated to offer the advantage of remodeling and fusing with the patient’s own vertebrae, it is well known in the art that cortical bone is so dense that it fuses poorly. It is not osteoconductive such that cells and vasculature have a difficult time entering the cortical bone to effect remodeling. See . Coates teaches the need to use “bone morphogenic protein” to induce remodeling. [Coates at col. 6, lines 19-20.] The prior art teaches that central cavity of an implant, such as a metal implant, is packed with cancellous chips or a bone paste that is osteoconductive and is readily remodeled so as to fuse with the adjacent vertebrae while the support member maintains support. Similarly, the central cavity of the polymer-reinforced implant of Siebels (or even the bone of Coates) can also be packed with this osteoconductive material (See Fig. 1 of Siebels) to allow a similar fusion that is obtained in Coates. Thus, Coates offers very little in the way of advantage over Siebels and the knowledge already in the art. Moreover, given Coates admitted “**extreme difficulty**” in producing a **single piece cortical bone implant**, versus the “**extraordinarily easy way**” of

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making the fiber-reinforced plastic implants of Siebels, one skilled in the art would not have been motivated to use the “extreme[ly] difficult” cortical bone of Coates to make even more difficult cortical bone implants from multiple tiny machined pieces of cortical bone that need to be assembled together and retain the strength and properties. For all these reason, one skilled in the art would not have been motivated by “superior properties in vivo” (because there is no showing of a plurality of “superior properties”) and because and minor superiority in a single property is more than offset by the relative ease in manufacturing with FRP versus the admitted difficulty with cortical bone.

For this reason also, the combination of Siebels over Coates would have failed to render obvious claims 26-34 and 61-62 of the Applicants’ invention at the time that the Applicants’ invention was made.

## SUMMARY

Claims 26-34 and 61-62 are pending and subject to rejection.

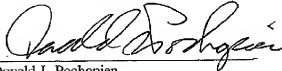
In view of the evidence, arguments and/or amendments herein, the rejection of claims 26-34 under 35 U.S.C. § 102 (b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot. In view of the evidence, arguments and/or amendments herein, the rejection of claims 61-62 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot. In view of the evidence, arguments and/or amendments herein, the rejection of claims 26-27, 31-34 and 61-62 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot. Finally, in view of the evidence and arguments herein, all bases for rejection of claims 26-34 and 61-62 under 35 USC § 103(a) over Siebels and Coates have been rebutted.

Claims 26-34 and 61-62 are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By:



Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8133

Date: August 25, 2006

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# EXHIBIT D



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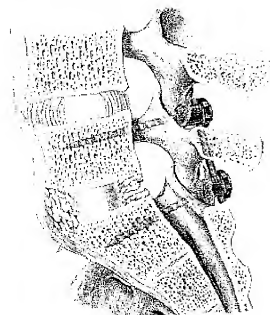
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A basic component of any spinal fusion is the bone graft. Bone grafting is used for many types of orthopedic procedures that require bone to heal. Bone grafting is used in two main ways during orthopedic procedures: 1) to stimulate the bone to heal, and 2) to provide support to the skeleton by filling in gaps between two bones.

The most common use of bone graft is to stimulate the healing of bone. The bone graft is used similar to "fertilizer" that stimulates the bone to heal and speeds up the process. When bone

tissue is crushed into powder and placed around a fracture or a fusion site, there are chemicals in the bone that stimulate the bone to heal. If the bone is taken from the person's own body, there may also be living bone cells (called osteocytes) that survive being transferred to the new location and continue to go about their business of making new bone. Even bone taken from someone else will stimulate bone to heal. Although, bone taken from the same person may be better because of the possibility of the bone graft having remaining live bone cells during the transfer.

The second way that bone graft is used is for structure. Rather than crush the bone into fine pieces, larger pieces of bone are used to fill a gap between two bones. For example, if the surgeon removes a vertebra or disc, and has a gap to fill, he may place a chunk of bone graft into the space. Because bone is rigid, it will hold the bones apart while the body grows to the chunk of bone graft at either end. Over time, the entire piece of bone that was grafted will be "remodeled" and replaced by the body with new bone. How long this takes depends on how big a piece of bone was used. It

is a slow process that may take years.

Bone taken from your own body is called autograft. Bone graft taken from someone else is called allograft. Allograft is usually removed from organ donors and placed in bone banks. The bone bank follows procedures intended to sterilize the bone graft and performs tests on the bone for diseases such as hepatitis and AIDS (just like a blood bank). The bone bank then sells the allograft to the hospital that performs your surgery. The cost will show up on your hospital bill.

An allograft can come from many types of bones in many different forms, but because it is not taken from the patient, it does not contain any living cells and has fewer chemicals to stimulate growth of new bone. The disadvantage of an allograft is that it does not always heal as well or as quickly as an autograft. However, a bone-growing protein can be added to the site to make up for the lack in the bone graft. The advantage is that the patient does not have to donate the bone graft, so the surgery is shorter, and there may be less postoperative pain. The allograft also carries a risk of transferring infectious diseases, although it is rigidly tested.

Allograft is very useful when the operation will require more bone graft than your own body can supply. Some major spine fusions need a lot of bone graft and the surgeon may mix allograft with autograft. Some surgeries need large pieces of structural bone graft and it would cause a problem in the area where the bone was removed if it were taken from your own body.

There has been a great deal of research to design bone graft substitutes, chemicals, and devices that can stimulate the bone to fuse and grow together. Electrical current has been known for some time to stimulate bone to grow, so many surgeons use electrical stimulation devices during the first weeks of surgery to speed up a fusion. Artificial bone graft materials have been developed. Sea Coral, harvested from oceans, has actually been used as the basis for a structural bone replacement very successfully.

Demineralized Bone Matrix (DBM) is a type of allograft that is developed from cadaver bones in a bone bank. The bone has the calcium removed and can be turned into a putty, sheet, or gel. The material can then be added to a graft site to improve the fusion. Bone Morphogenic Protein (BMP) is an additional material that has been developed recently. BMP is a chemical that is added to bone graft and enhances bone growth when it is added to a fusion site.

Your surgeon will try to promote and speed the healing of your spinal fusion in a number of ways. The most common approach is to use your own bone whenever possible - it seems to be best at getting bone to heal. Allograft may be used to reduce your risks of problems with taking the bone graft from your body when more bone graft is needed than your body can supply.

Be sure to discuss the different options with your surgeon.

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# EXHIBIT G

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SECOND COLLEGE EDITION

WEBSTER'S  
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# EXHIBIT H



US005192327A

## United States Patent [19]

[11] Patent Number: 5,192,327

Brantigan

[45] Date of Patent: Mar. 9, 1993

## [54] SURGICAL PROSTHETIC IMPLANT FOR VERTEBRAE

[76] Inventor: John W. Brantigan, 328 Overlook Brook Ct., Chagrin Falls, Ohio 44022

[21] Appl. No.: 673,474

[22] Filed: Mar. 22, 1991

[51] Int. Cl.<sup>5</sup> ..... A61F 2/44

[52] U.S. Cl. .... 623/17; 606/60;

[58] Field of Search ..... 623/17; 606/60, 61

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Primary Examiner—Randall L. Green

Assistant Examiner—Dinh Nguyen

## [57]

## ABSTRACT

Surgical prosthetic modular implants used singularly or stacked together are provided to support and fuse together adjacent vertebrae or to totally or partially replace one or more vertebrae in a vertebral column. The implants are rigid annular plugs, dimensionally similar to normal vertebral bodies, have simplified oval or hemi-oval shapes with ridged faces to engage adjacent vertebral bodies to resist displacement and allow bone ingrowth and fusion and to interdigitate with the ridges of an adjacent plug for modular stacking to allow variability of ultimate implant height. The implants can be provided in sets of different thicknesses and are internally grooved to receive an upstanding connecting bar to bind together the individual stacked implants into a stable unit. The annular implants have ample spaces to allow ingrowth of blood capillaries and packing of bone graft and are preferably made of a radiolucent material, preferably biocompatible carbon fiber reinforced polymers or are alternately made of traditional orthopaedic implant materials such as nickel, chromium, cobalt, stainless steel or titanium.

14 Claims, 3 Drawing Sheets

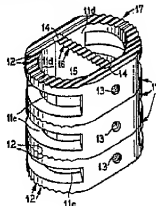


FIG. 1

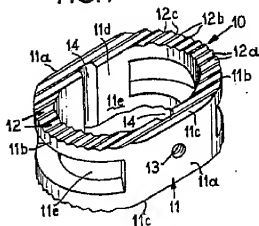


FIG. 2

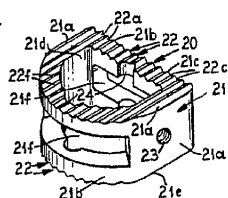


FIG. 3

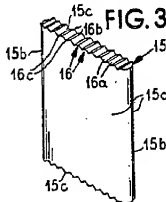


FIG. 4

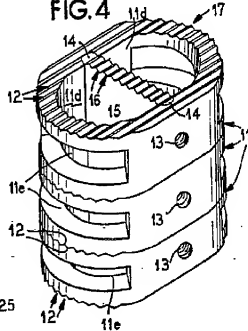
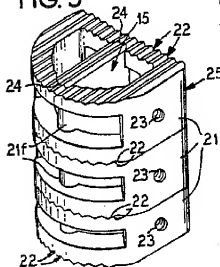
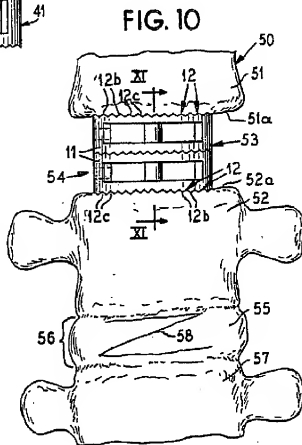
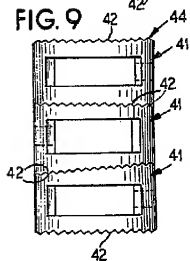
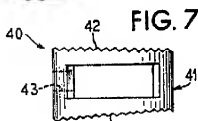
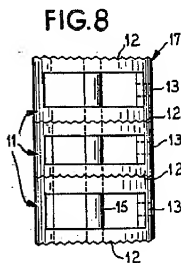
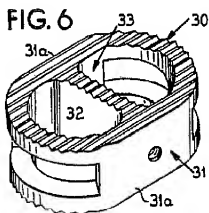


FIG. 5







# SURGICAL PROSTHETIC IMPLANT FOR VERTEBRAE

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention

This invention relates to inert rigid vertebral prosthetic devices and methods for treating the devices between adjacent vertebrae to treat or prevent back or neck pain in patients with ruptured or degenerated intervertebral discs and for replacing vertebral bodies damaged by fracture, tumor or degenerative process. Specifically, the invention deals with ring-like prosthetic plugs or discs used singly or stacked together between vertebrae to form support stunts in the spinal column and having rigid surfaces facilitating anchoring and providing valleys for bone ingrowth from adjoining vertebrae. The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies, are supplied in different heights to be used individually to replace a single damaged intervertebral disc, have ridges to bite into the vertebrae or to interdigitate to be securely stacked together to the exact height required at the time of surgery, have slots and hollow areas for packing bone graft material, tool receiving means, and are preferably radiolucent to allow visualization of the bone healing postoperatively.

### 2. Description of the Prior Art

While many types of vertebral prosthetic devices have been proposed, the success ratio has been very low and the surgical procedures have been very complicated and traumatic to the patient. The surgical implant devices and methods covered in my U.S. Pat. Nos. 4,743,256; 4,854,757 and 4,878,915 have greatly improved the success rate and have simplified the surgical techniques in interbody vertebral fusion. In the procedures covered by these patents, biologically acceptable but completely inert strut plugs are bottomed in channels or grooves of adjoining vertebrae and receive bone ingrowth which quickly fuses the structure to the bone and forms a living bone bridge across the fusion area.

The present invention now further improves this art of interbody fusion without cutting grooves or channels in the vertebrae and is especially well suited for anterior cervical and lumbar fusion. The invention provides ring-like prosthesis plugs or discs bottomed on end faces of adjoining vertebrae and constructed and arranged so that they can be used singly or stacked plurally to accommodate individual surgical requirements. The rings can replace excised discs and vertebrae and can also be mounted inside the fibrous disc column connecting adjoining vertebrae. The annular units are preferably oval or partial oval shaped preferably hemi-oval, to conform with vertebral disc shapes, have ridged or peaked surfaces for biting into the vertebrae on which they are seated and for receiving bone ingrowth in valleys between the peaks. When stacked, an interior connecting bar can be provided to lock the components in fixed relation and cooperate with interfitting ridges.

## SUMMARY OF THE INVENTION

According to this invention, biologically acceptable, but inert rigid annular prosthesis units are provided to support and fuse with adjacent vertebrae in both the cervical, thoracic spine and lumbar portions of a human vertebral column. These ring-like prosthetic devices are

bottomed on the hard bone faces or end plates of adjacent vertebrae and are generally oval shaped to conform with the general outline perimeters of the vertebrae. They are also provided in partial (preferably hemi-oval) annular shape to accommodate those surgical procedures where only a portion of the vertebrae or disc is damaged. Two such hemi-oval rings can be used in the posterior lumbar area in side-by-side relation since the dorsal sac and nerve roots must be retracted to each side in turn as the implant is placed on the opposite side. In an anterior fusion since the entire front of the disc space is exposed, a single piece implant can be used making the oval an advantage in this area.

The periphery of the oval ring is grooved to accommodate ingrowth of blood capillaries and the open central portion of the ring is preferably packed with bone graft material to facilitate bone ingrowth. Bone graft can also be packed in the grooves.

Each of the oval implants is sized to match the height of an average disc and thus, can vary from 10 to 15 mm for the lumbar area and from 7-11 mm for the cervical area.

The oval shape simplifies the surgical procedure since it can be rotated or reversed and still fit the vertebrae. Further, the device stretches the disc tissue creating a tension which will cause the vertebrae to tightly grip the ring on which it is bottomed. If the disc columnar tissue is preserved, a cut, preferably "Z"-shaped, can be made in the columnar fibrous tissue, the interior pulposus material of the disc removed, and the ring implant inserted through the cut to be bottomed on the adjoining vertebrae and surrounded by the disc tissue.

To accommodate a myriad of different heights between vertebrae on which the prosthesis ring is to be bottomed, the rings can be supplied in sets of different heights to be stacked to the exact height required for a particular surgical implant. For example, in the cervical spine, cervical corpectomy is often required for cervical myelopathies in which large bone spurs cause spinal cord pressure. An average grafting height is 30 mm after corpectomy and this can be achieved by stacking, for example, three 10 mm high oval implants.

In the treatment of thoracic columnar fractures, hemi-corpectomy is often done followed by grafting. Placement of stacked hemi-oval implants in the hemi-corpectomy area provides solid structural weight bearing. The re-sected vertebral bone is packed into the implant so that harvesting of additional bone grafting can be avoided.

In the treatment of vertebral tumors, the stacked oval implants can achieve solid bony fusion across the entire re-sected area providing a permanent mechanically secure repair with living tissue.

The invention now provides vertebral prosthetic implant devices suitable for anterior, posterior or lateral placement in any area of the spine requiring replacement of disc or vertebral body. Since the implants are intended to bottom out on adjacent vertebral end faces, which preferably have been prepared by flattening with a burr drill, removing cartilaginous material and stretching the annular fibrosis so that the vertebrae can tightly grip the plug, the plugs can be inserted either anteriorly, posteriorly or laterally into the vertebral column while mounted on the end of an insertion tool.

The ring devices have ridged surfaces providing multiple purposes of gripping the vertebrae to resist expul-

sion, forming valleys to facilitate bone ingrowth, and to matching interdigitate with each other for stacking.

An upstanding longitudinal connecting member fits in interior grooves in the ring and cooperates with the ridges to prevent separation of stacked implants in every direction except in longitudinal height. Since the implants are placed in compression between the vertebral bodies, they cannot come apart after implantation.

The implants are preferably made of radiolucent material such as carbon fiber reinforced polymers known commercially as "Peek", (polyetherether ketone) or "Ultrapek" (polyether ketone, ether ketone, ketone). Alternately, polycarbonate, polypropylene, polyethylene and polysulfone type plastics material filled with glass or carbon fibers can be used. Such materials are supplied by ICI Industries of Wilmington, Del.; Fiber-Rite Corporation of Waconia, Minn. or BASF Corporation.

Preferred best mode embodiments of the invention are illustrated in the attached drawings in which:

FIG. 1 is a top and side perspective view of a full oval prosthetic device according to this invention;

FIG. 2 is a top and side perspective view of a hemi-oval prosthetic device of this invention;

FIG. 3 is a top and side perspective view of a connecting bar fitting the illustrated grooves in the devices of FIGS. 1 and 2 to hold a plurality of the devices in stacked relation;

FIG. 4 is a top and side perspective view of a stack of the devices of FIG. 1 with the connecting bar of FIG. 3 in place;

FIG. 5 is a top and side perspective view of a stack of the devices of FIG. 2 with a connecting bar like FIG. 3 in place;

FIG. 6 is a view similar to FIG. 1 but illustrating a modified device with an integral cross bar;

FIG. 7 is a side view showing a tapered device of this invention;

FIG. 8 is a side view of the stack of devices of FIG. 4 showing how the ridges interdigitate when stacked;

FIG. 9 is a view similar to FIG. 8 but showing a stack of tapered devices of FIG. 7 with the center device rotated 180° to form a vertical stack with end faces tapered in the same direction.

FIG. 10 is an elevational view of a portion of a vertebral column showing a two stack assembly in an excised disc space between adjacent vertebrae and the manner in which a disc can be cut to receive a device of this invention.

FIG. 11 is a sectional view along the line XI—XI of FIG. 10;

FIG. 12 is a longitudinal view of a portion of a vertebral column, with parts in section and broken away to show the manner in which a stack of the devices is used to replace partially damaged discs and an intermediate vertebral portion;

FIG. 13 is a side diagrammatic view showing the insertion of a device of this invention in a disc space with the aid of a mounting tool.

FIG. 14 is a view similar to FIG. 13 illustrating the manner in which a fork-like tool can have discs mounted in a pair of holes in the device.

FIG. 15 is a line diagram illustrating the manner in which the ridges of the plugs have side walls diverging at the same angles from the peaks to provide interdigitating or complimentary mating or nesting projections.

As shown on the drawings:

In FIG. 1, the reference numeral 10 designates generally a vertebrae prosthesis device of this invention composed of rigid biologically acceptable and inactive material, preferably a radiolucent plastics material, inert metal and the like as described above. The device 10 is an oval ring plug 11 generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column. The plug 11 has opposed sides 11a and ends 11b, flat, ridged top and bottom faces 11c and a central upstanding aperture 11d therethrough. The ends 11b have relatively wide and long horizontal peripheral slots 11e therethrough preferably extending into the sides 11a and communicating with the central aperture 11d.

Ridges 12 are formed longitudinally across the end faces 11c. These ridges 12 have inclined side walls 12a merging at sharp peaks 12b and provide valleys 12c between the side walls. The valleys 12c open at the ends 11b of the oval ring plug 11.

One side wall 11c of the plug 11 has an internally threaded hole 13 extending partially through the wall for receiving a mounting tool as hereinafter described.

The interior faces of the side walls 11a also have upstanding open ended vertical grooves 14 preferably of fragmental cylindrical configuration. These grooves are provided for mounting a rectangular connecting bar 15 shown in FIG. 3. This bar 15 has flat side faces 15a, rounded side edges 15b to snugly fit the grooves 14 and top and bottom end edges 15c which are provided with ridges 16 that conform with the ridges 12 of the plug 10.

Thus, these ridges 16 have oppositely inclined sides 16a converging to peaks 16b and providing valleys 16c therebetween. The peaks and valleys of the ridges on the ends of the connecting bar 15 are aligned with the peaks and valleys of the ridges on the top and bottom faces 11c of the plug 11 when the bar is seated in place in the grooves 14.

The connecting bar 15 has a height conforming with the total height of a stack 17 of plugs 11 shown in FIG. 4 or with only a single plug 11 if a stack of plugs is not necessary. As shown in FIG. 4 three plugs 11 are stacked together with the ridges 12 of the intermediate plug nested in and interdigitating with the ridges of top and bottom plugs. These ridges interfit to provide a stable stack and the connecting bar 15 seated in the aligned grooves 14 of the three plugs will prevent shifting of the stack. The end faces of the bars 15 will then have their ridges 16 aligned with the ridges 12 in the exposed end faces of the top and bottom plugs 11.

The central aperture 11d of each plug 11 is separated by the bar 15 into two side-by-side chambers which are easily packed with bone graft material to expedite the fusion of the prosthesis device in the spinal column. In addition, the slots 11e in the ends 11b of the plugs can receive bone graft material and also provide free spaces for blood flow to speed up the fusion process.

A modified hemi-oval device 20 is illustrated in FIG. 2 for use in partial corpectomy operations and also for use in spaced side-by-side relation when an intermediate nerve space is needed. The device 20 is a one-piece plastic material or metal plug 21 of generally hemi-oval shape with opposed side walls 21a, a rounded oval end wall 21b, a flat opposite end wall 21c and a central aperture 21d. The top and bottom faces 21e of the plug 21 are ridged in the same manner as the plug 11 thus providing longitudinal ridges 22 with inclined side walls 22a, peaks 22b and valleys 22c. The end walls 21b and 21c have the same slots 21e as the slots 11e of the plug 11

and an end wall 21a has the same tool receiving recess 23 as the plug 11.

Internal grooves 24 are provided in the inner faces of the end walls 21b and 21c of the plug 21 to receive a connecting bar such as 15. This bar however will divide the central aperture of the plug 21 in a longitudinal instead of a transverse direction as illustrated for the plugs 11.

As shown in FIG. 5 the plugs 21 form a stack 25, in the same manner as the plugs 11 in the stack 17 of FIG. 4 with the same type of connecting bar 15.

The plugs 11 and 21 of FIGS. 1 to 5 may vary in thickness or height to suit conditions and in the stacks of FIGS. 4 and 5, plugs of different thicknesses or heights can be stacked together to provide the desired overall height for each operation. Sets of these plugs may thus be supplied so that the surgeon can easily end up with a stack of the required height to fit the patient. The lengths or heights of the connecting bars 15 can also be varied to suit conditions or can be ground down at the time of the operation to match the stack.

The ridges on the exposed end faces of the stacks of plugs will bottom on the hard end faces or end plates of adjacent vertebrae and the apices or peaks 21b and 22g of these ridges will firmly engage and bite into these faces to prevent slippage. In addition, the valleys 12c and 22c between the ridges serve as gaps or troughs to freely receive bone ingrowth from the adjacent vertebrae.

The individual plugs or the stack of plugs can be introduced anteriorly, laterally or posteriorly depending upon conditions and the tool receiving recesses 13 and 23 of the plugs 11 and 21 can thus be positioned to meet the particular type of insertion into the vertebral column.

Instead of providing a separate bar or plate 15, as shown in FIG. 6, a modified device 30 of this invention is a plug 31 of the same oval shape as the plug 11 of FIGS. 1 and 4 but the reinforcing bar 32 of this plug is integral with its side walls 31a. The hollow interior 23 of the plug 31 is thus bisected by an integral internal partition 32 forming a pair of side-by-side apertures through the plug adapted to receive bone graft material.

A plug similar to 30 can also be provided in a hemi-oval shape. The plugs with the integral dividing bars are preferably used singly but also can be stacked and interdigitated by their ridges.

The plugs 11, 21 and 31 of FIGS. 1, 2 and 6 are uniform in thickness or height across their length.

In a further modified device 40 shown in FIG. 7, the plug 41 is tapered to be higher or thicker at its anterior end than at its posterior end. The plug 41 has ridged top and bottom faces 42, the same as the plugs of FIGS. 1-6 and a tool receiving recess 43 is provided in its higher or trailing end. By way of an example, the trailing end could be 12 mm in height while the leading end reduced to 9 mm in height.

In the stacking of plugs, each of which have uniform height or thickness such as shown at 11, 21, and 31, the holes for the mounting tool can all be aligned on one side of the stack as illustrated in FIG. 8 but, as shown in FIG. 9, the forming of a stack 44 of tapered plugs 41 requires displacement of the central or middle plug 180' from the end plugs in order that the stack will have a vertical column contour. The ridged faces 42 of the tapered plugs 41 will interdigitate and the exposed end faces of these ridges will be inclined or tapered to suit surgical application in spaces where the adjacent vertebrae

are wider at one end than at the other. The use of the tapered plugs eliminates some of the grinding of the end faces of the vertebrae that may be needed for a good matching of the ridges with the vertebrae faces.

As shown in FIG. 10, a portion of a human vertebral column 50 has adjoining vertebrae 51 and 52 fused together by a two-unit stack 53 composed of the plugs 11 illustrated in detail in FIGS. 1, 4 and 8. This stack 53 fits the disc space 54 between the vertebrae 51 and 52 and the top ridges 12 of the stack are bottomed on and bite into the bottom face or hard end plate of the upper vertebrae 51 while the bottom ridges 12 of the stack are bottomed on and bite into the upper face or hard end plate 52a. The peaks 12b of the ridges 12 firmly anchor the stack to the vertebrae but do not penetrate through the hard faces 51a and 52a of the vertebrae. The valleys 12c are exposed to the vertebrae faces and receive bone ingrowth from the vertebrae during the post-operative fusion.

As shown all of the disc has been removed from the disc space 54 and the stack 53 maintains the disc space at its normal height.

As shown in FIGS. 10 and 11, a vertebral disc 55 fills the disc space 56 between the vertebrae 52 and a lower vertebrae 57 of the vertebral column 58. A Z-shaped cut 58 through the tubular fibrous portion of the disc 55 provides access to the interior pulposus portion of the disc permitting its removal to receive a single plug 11 forming a rigid strut inside of the column of disc fibers 55a which remain attached to the bottom face 52b of the upper vertebrae 52 and the top face 57a of the lower vertebrae 57. As illustrated, the peaks 12b of the ridges 12 on the top and bottom faces of the plug 11 bite into the faces 52b and 57a and the valleys 12c between the peaks are openly exposed to these faces of the vertebrae.

As better shown in FIG. 11, the hollow interior 11d and the slots 11e of the plug 11 are packed with bone graft material 58 which can be conveniently harvested from the iliac crests of the patient's pelvic bone.

FIG. 12 illustrates a cervical portion 60 of a human vertebral column having an upper vertebrae 61, a middle vertebrae 62 and a bottom vertebrae 63 with a stack 25 like FIG. 5 but composed of four plugs 21 implanted to support the column. As shown, the top and bottom vertebrae 63 remain intact while the middle vertebrae 62 has been partially excised. The four hemi-oval plug units 21 are interdigitated together through their ridges 22 and a bar 15 such as shown in FIG. 5 can hold the units in an upright column. Discs 64 and 65 have also been partially excised to receive the adjacent vertebrae. The remaining tissue is anchored to their adjacent vertebrae.

The bottom face 61a of the upper vertebrae 61 and the top face 63a of the bottom vertebrae 63 are partially penetrated by the peaks of the ridges of the top and bottom plugs 21 to function as described above. Also, the hollow interiors of the hemi-oval plugs 21 and their slots 21e are filled with bone graft material 66.

During surgery, the spinal column is stretched to regain any lost disc space caused by herniation of the discs. This stretches the remaining disc tissue and as illustrated in FIGS. 13 and 14, the plugs of this invention such as the plugs 11 or a stack of the plugs, are inserted into the opened up disc space such as 70 between adjacent vertebrae 71 and 72, either anteriorly, laterally or posteriorly while mounted on a tool 73 having a single end 73a threaded into the internally threaded hole 13 of the plug 11 as illustrated in FIG. 13.

Alternately, the plug 11, as illustrated in FIG. 14 may have a pair of side-by-side holes 13c receiving the line end 74 of a modified tool 75.

Tools such as 73 and 75 may also be replaced with other gripping tools which do not require amounting apertures in the end faces of the plugs.

As better shown in the line diagram of FIG. 15 the ridged faces such as 12 of two stacked plugs such as 11 of FIG. 1 have equally inclined side walls 12a diverging from sharp peaks 12b at a relatively wide angle A to prevent formation of this narrow fingers or teeth that could break off and narrow valleys that could block bone ingrowth. An angle of at least 30°-45° is preferred to provide wide ridges and open valleys.

From the above description, it will be understood that this invention now advances the art of vertebral column surgery and provides prosthetic devices used singly or stacked to desired heights, which fit the disc spaces between adjacent vertebrae, bottom on and bite into the vertebrae faces without penetrating the hard surfaces thereof and have ample chambers for ingrowth of blood capillaries and bone graft material to expedite bone ingrowth during a post-operative period. The devices do not require anchoring screws or penetration through the hard faces of the vertebrae and can be mounted inside the vertebral disc or along the side of a partially excised disc, or in the disc space of a completely excised disc.

I claim as my invention:

1. A prosthetic device to integrate with and support vertebrae in a vertebral column which comprises a plurality of inert generally oval shaped rings conforming in shape and size with hard end plates of vertebrae on which it is to be seated, each of said rings having ridged top and bottom faces adapted to selectively interdigitate with surfaces of adjacent rings to form a stack and having peaks to bite into the end plates of adjoining vertebrae together with valleys between the peaks to receive bone ingrowth from the vertebrae for fusing the vertebrae together through the rings.

2. The device of claim 1, wherein the peaks have side walls diverging at an angle of not substantially less than about 30°.

3. The device of claim 1, wherein the top and bottom faces of the rings fully mate together when the rings are used in a stack.

4. A prosthetic device for vertebral fusion which comprises a stack of annular rigid inert plugs having interiors and interdigitated ridged faces holding the plugs against displacement in the stack and ridged exposed end faces for bottoming on adjoining vertebrae, and a connecting bar extending through the stack holding the plugs in aligned position in the stack.

5. The prosthetic device of claim 4, wherein each of the plugs have diametrically opposed internal upstanding grooves receiving the connecting bar.

6. The prosthetic device of claim 4, wherein the plugs have an internal connecting bar divides the interiors of the annular plugs into side by side compartments.

7. A surgical prosthetic device adapted for fusing together adjoining vertebrae in a vertebral column which comprises a rigid inert annular plug sized and shaped to fit opposed end faces of vertebrae in a vertebral column and having top and bottom faces with peaks adapted to bite into the end faces of the adjoining vertebrae and valleys between the peaks to receive bone ingrowth, said plug selected from the group consisting of oval and hemi-oval rings, and said plug having a

height effective to provide a strut between the vertebrae maintaining a desired disc space.

8. A surgical prosthetic device adapted for fusing together adjoining vertebrae in a vertebral column which comprises a rigid inert annular plug sized and shaped to fit opposed end faces of vertebrae in a vertebral column and having top and bottom faces with peaks adapted to bite into the end faces of the adjoining vertebrae and valleys between the peaks to receive bone ingrowth; said plug having a height effective to provide a strut between the vertebrae maintaining a desired disc space, and said height of the annular plug being sufficient to stretch a annulus fibrosis tissue of a disc connecting the adjoining vertebrae to maintain a desired disc height and provide snug gripping of the plug with the end faces of the adjoining vertebrae.

9. The surgical prosthetic device of claim 8 wherein the top and bottom faces of the plug have diverging equally sloping side walls converging to sharp peaks and relatively wide valleys between the peaks and said side walls adapted to nest together to hold adjacent plugs in alignment.

10. A surgical prosthetic device adapted for fusing together adjoining vertebrae in a vertebral column which comprises a rigid inert annular plug having an interior and sized and shaped to fit opposed end faces of vertebrae in a vertebral column and having top and bottom faces with peaks adapted to bite into the end faces of the adjoining vertebrae and valleys between the peaks to receive bone growth, said plug having a height effective to provide a strut between the vertebrae maintaining a desired disc space, and said plug having a bar intersecting the interior of the plug.

11. The surgical prosthetic device of claim 10 having diametrically opposed upstanding internal grooves adapted to receive said bar.

12. A prosthetic device seating on hard end plates of vertebrae in a vertebral column while preserving healthy disc tissue between the vertebrae which comprises a rigid inert annular plug generally conforming in shape and size with opposing hard end plates of vertebrae on which it is to be seated, said plug having peripheral side and end walls, top and bottom faces, a central aperture therethrough between the faces, and a peripheral slot therein, said end faces having raised ridges with side walls converging to peaks and valleys between the side walls, said peaks adapted to be bottomed on and bite into the hard end plate faces of vertebrae, tool mounting means in a peripheral wall of the plug, said aperture and slot in the plug adapted to be packed with bone graft material, and said plug being composed of a radiolucent plastics material.

13. A prosthetic device seating on hard end plates of vertebrae in a vertebral column while preserving healthy disc tissue between the vertebrae which comprises a rigid inert annular plug generally conforming in shape and size with opposing hard end plates of vertebrae on which it is to be seated, said plug having peripheral side and end walls, top and bottom faces, a central aperture therethrough between the faces, and a peripheral slot in each end wall therein, said end faces having raised ridges with side walls converging to peaks and valleys between the side walls, said peaks adapted to be bottomed on and bite into the hard end plate faces of vertebrae, tool mounting means in a peripheral wall of the plug, and said aperture and slot in the plug adapted to be packed with bone graft material.

14. A prosthetic device seating on hard end plates of  
vertebrae in a vertebral column while preserving  
healthy disc tissue between the vertebrae which com-  
prises a rigid inert annular plug generally conforming in  
shape and size with opposing hard end plates of vertebrae  
on which it is to be seated, said plug having peripheral  
side and end walls, top and bottom faces, a central  
aperture therethrough between the faces, and a peripheral  
slot therein, said end faces having raised ridges with  
side walls converging to peaks and valleys between the

side walls, said peaks adapted to be bottomed on and  
bite into the hard end plate faces of vertebrae, tool  
mounting means in a peripheral wall of the plug, said  
aperture and slot in the plug adapted to be packed with  
bone graft material and said plug having an anterior  
portion higher than the posterior portion to provide a  
wedging effect when inserted into position between the  
hard end plate faces of the vertebrae.

\* \* \* \* \*

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UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 5,192,327  
DATED : March 9, 1993  
INVENTOR(S) : John W. Brantigan

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 8:

Claim 8, line 11 "a annulus" should read --annulus--.

line 14, "and faces" should read --end faces--.

Signed and Sealed this

Thirtieth Day of August, 1994

Attest:



BRUCE LEEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

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# EXHIBIT I



Welcome, Donald!

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		SGL Carbon Group 30% SIGRAFIL C® - filled PEEK	Overview - Polyetherketone/ethersulfone/PEEK/KV Carbon Fiber Filled	Overview - Polycarbonate/Carbon Fiber Reinforced
<b>Physical</b>				
1	<input checked="" type="checkbox"/> Density (g/cc)	1.4	1.33 - 1.41	1.21 - 1.39
2	<input checked="" type="checkbox"/> Water Absorption (%)	0.17	0.1 - 0.2	0.08 - 0.2
3	<input checked="" type="checkbox"/> Linear Mold Shrinkage (cm/cm)	--	0.0005 - 0.001	0.0005 - 0.0053
4	<input checked="" type="checkbox"/> Linear Mold Shrinkage, Transverse (cm/cm)	--	0.015	
<b>Mechanical</b>				
5	<input checked="" type="checkbox"/> Hardness, Rockwell R	--	183 - 269	118 - 120
6	<input checked="" type="checkbox"/> Tensile Strength, Ultimate (MPa)	218	183 - 200	183 - 200

7	<input type="checkbox"/> Tensile Strength, Yield (MPa)			110
8	<input type="checkbox"/> Elongation at Break (%)	1.6	1.4 - 2.5	1.5 - 8
9	<input type="checkbox"/> Modulus of Elasticity (GPa)		12.4 - 26.2	4.8 - 24.1
10	<input type="checkbox"/> Flexural Modulus (GPa)	17.8	6.9 - 21.4	4.1 - 21.4
11	<input type="checkbox"/> Flexural Yield Strength (MPa)	297	270 - 379	124 - 296
12	<input type="checkbox"/> Compressive Yield Strength (MPa)			114 - 152
13	<input type="checkbox"/> Izod Impact, Notched (J/cm)		1 - 1.1	0.48 - 1.87
14	<input type="checkbox"/> Izod Impact, Notched (ISO) (kJ/m <sup>2</sup> )	9		
15	<input type="checkbox"/> Izod Impact, Unnotched (J/cm)		8 - 9.1	2.94 - 9.5
16	<input type="checkbox"/> Izod Impact, Unnotched (ISO) (kJ/m <sup>2</sup> )	43.2		
17	<input type="checkbox"/> K (wear) Factor		5000	
<b>Electrical</b>				
18	<input type="checkbox"/> Electrical Resistivity (ohm-cm)	5500	10000	5 - 1e+010
19	<input type="checkbox"/> Surface Resistance (ohm)			5 - 1e+010
<b>Thermal</b>				
20	<input type="checkbox"/> CTE, linear 20°C (unim-°C)			13 - 31
21	<input type="checkbox"/> Thermal Conductivity (W/m-K)			0.55 - 0.72
22	<input type="checkbox"/> Maximum Service Temperature, Air (°C)			100 - 149
23	<input type="checkbox"/> Deflection Temperature at 0.46 MPa (66 psi) (°C)			141 - 151
24	<input type="checkbox"/> Deflection Temperature at 1.6 MPa (264 psi) (°C)		271 - 354	100 - 149

25	<input type="checkbox"/> Glass Temperature (°C)	150
26	<input type="checkbox"/> Flammability, UL94	HB - V-0
<b>Processing</b>		
27	<input type="checkbox"/> Processing Temperature (°C)	300 - 318
28	<input type="checkbox"/> Mold Temperature (°C)	85 - 121
29	<input type="checkbox"/> Drying Temperature (°C)	120
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## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	09782594			
<b>Filing Date:</b>	12-Feb-2001			
<b>Title of Invention:</b>	Assembled Implant			
<b>First Named Inventor:</b>	John R. Bianchi			
<b>Filer:</b>	Donald J. Pochopien/Deborah Wilson			
<b>Attorney Docket Number:</b>	RTI- 112R			
Filed as Large Entity				
<b>Utility      Filing Fees</b>				
<b>Description</b>	<b>Fee Code</b>	<b>Quantity</b>	<b>Amount</b>	<b>Sub-Total in USD(\$)</b>
<b>Basic Filing:</b>				
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<b>Extension-of-Time:</b>				
Extension - 3 months with \$0 paid	1253	1	1020	1020

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				1020

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	1172652
<b>Application Number:</b>	09782594
<b>Confirmation Number:</b>	9490
<b>Title of Invention:</b>	Assembled implant
<b>First Named Inventor:</b>	John R. Bianchi
<b>Correspondence Address:</b>	DONALD J. POCHOPIEN McANDREWS, HELD & MALLOY, LTD. CITICORP CENTER, 34TH FLOOR 500 WEST MADISON STREET CHICAGO IL 60661 US 4072280329 -
<b>Filer:</b>	Donald J. Pochopien/Deborah Wilson
<b>Filer Authorized By:</b>	Donald J. Pochopien
<b>Attorney Docket Number:</b>	RTI- 112R
<b>Receipt Date:</b>	25-AUG-2006
<b>Filing Date:</b>	12-FEB-2001
<b>Time Stamp:</b>	16:12:34
<b>Application Type:</b>	Utility
<b>International Application Number:</b>	

### Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	\$1020

RAM confirmation Number	203
Deposit Account	130017
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1		13980US02Amendment08-25-2006.pdf	3718729	yes	50
	Multipart Description				
	Doc Desc		Start	End	
	Transmittal letter		1	1	
	Fee Worksheet (PTO-875)		2	2	
	Extension of Time		3	3	
	Information Disclosure Statement (IDS) Filed		4	6	
	Amendment - After Non-Final Rejection		7	7	
	Claims		8	10	
	Applicant Arguments/Remarks Made In an Amendment		11	50	
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	8121	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			3726850		

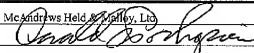
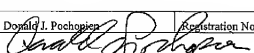
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

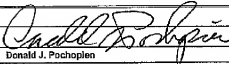
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)		Application Number	09/782,594
		Filing Date	February 12, 2001
		First Named Inventor	Bianchi, John R., et al.
		Art Unit	3738
		Examiner Name	Paul B. Preblich
Total Number of Pages in This Submission	50	Attorney Docket Number	RTI 112R /1915-13980US02
<b>ENCLOSURES (check all that apply)</b>			
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment And Response Under 37 CFR §1.111 <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	
		<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Return-Receipt Postcard <input type="checkbox"/> Other Enclosure(s) (please identify below):	
Remarks			
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>			
Firm	McAndrews Held, Kottay, Ltd.		
Signature			
Printed Name	Donald J. Pochopien, Reg. NO. 32,167		
Date	August 25, 2006		
<b>CERTIFICATE OF ELECTRONIC FILING</b>			
I hereby certify that this correspondence is being sent via electronic filing to Commissioner For Patents, Mail Stop Amendment, on August 25, 2006.			
Name (Print/type)	Donald J. Pochopien	Registration No. (Attorney/Agent)	32,167
Signature			Date August 25, 2006

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004 Fees pursuant to the consolidated Appropriates Act, 2005 (H.R. 4818). <h2 style="margin: 0;">FEE TRANSMITTAL</h2> <h3 style="margin: 0;">for FY 2006</h3>		<b>Complete if Known</b>					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number: 09/782,594	Filing Date: February 12, 2001				
<b>TOTAL AMOUNT OF PAYMENT</b> (\$) 1020.00		First Named Inventor: Bianchi, John R., et al.	Examiner Name: Paul B. Preblich				
<b>METHOD OF PAYMENT</b> (check all that apply)		Art Unit: 3738	Attorney Docket No.: RT1 112R/1915-13960US02				
<input type="checkbox"/> Check <input type="checkbox"/> Credit Card <input type="checkbox"/> Money Order <input type="checkbox"/> None <input type="checkbox"/> Other (please identify): _____							
<input checked="" type="checkbox"/> Deposit Account Deposit Account Number: <u>13-0017</u> Deposit Account Name: <u>McAndrews Held &amp; Malloy</u> For the above-identified deposit account, the Director is hereby authorized to (check all that apply)							
<input checked="" type="checkbox"/> Charge Fee(s) indicated below <input type="checkbox"/> Charge Fee(s) indicated below, except for the filing fee							
<input checked="" type="checkbox"/> Charge any additional fee(s) or underpayments of fees(s) <input checked="" type="checkbox"/> Credit any overpayments under 37 CFR 1.16 and 1.17							
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.							
<b>FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)</b>							
<b>1. BASIC FILING, SEARCH, AND EXAMINATION FEES</b>							
Application Type	Filing Fees Fee (\$)	Small Entity Fee (\$)	Search Fees Fee (\$)	Small Entity Fee (\$)	Examination Fees Fee (\$)	Small Entity Fee (\$)	Fees Paid (\$)
Utility	300	150	500	250	200	100	_____
Design	200	100	100	50	130	65	_____
Plant	200	100	300	150	160	80	_____
Reissue	300	150	500	250	600	300	_____
Provisional	200	100	0	0	0	0	_____
<b>2. EXCESS CLAIM FEES</b>							Small Entity
<b>Fee Description</b>							Fee (\$)
Each claim over 20 (including Reissues)							50
Each independent claim over 3 (including Reissues)							25
Multiple dependent claims							360
<b>Total Claims</b> <u>-20 or HP</u> x <u>_____</u> = <u>_____</u>							Multiple Dependent Claims
HP = highest number of total claims paid for, if greater than 20							Fee
<b>Indep. Claims</b> <u>-3 or HP</u> x <u>_____</u> = <u>_____</u>							Fee Paid (\$)
HP = highest number of independent claims paid for, if greater than 3							_____
<b>3. APPLICATION SIZE FEE</b>							
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
<b>Total Sheets</b> <u>-100</u> / <u>50</u> (round up to a whole number) x <u>_____</u> = <u>_____</u>							
<b>4. OTHER FEE(S)</b>							
Non-English Specification, \$130 fee (no small entity discount)							
Other (e.g., late filing surcharge): <u>Petition for 3 month extension of time</u>							
1020.00							
<b>SUBMITTED BY</b>							
Signature				Registration No. (Attorney/Agent)	32,167	Telephone	(312)775-8000
Name (print/type)	Donald J. Pochopien			Date	August 25, 2006		

<b>PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)</b> <b>FY 2005</b> <i>(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)</i>		Docket Number (Optional) RTI 112R/1915-13980US02	
Application Number 09/782,594		Filed February 12, 2001	
For "Assembled Implant"			
Art Unit 3738		Examiner Paul B. Preblich	

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	<u>Fee</u>	<u>Small Entity Fee</u>	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ _____
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$ _____
<input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$1020.00
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$ _____
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$ _____

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 13-0017. I have enclosed a duplicate copy of this sheet.

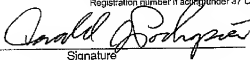
**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

I am the ☐ applicant/inventor.  
☐ assignee of record of the entire interest. See 37 CFR 3.71

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number 32,167  
☐ attorney or agent under 37 CFR 1.34.

Registration number if agent under 37 CFR 1.34: \_\_\_\_\_

  
 \_\_\_\_\_  
 Signature  
 Donald J. Pochopien, Reg. No. 32,167  
 \_\_\_\_\_  
 Typed or printed name

August 25, 2006  
 \_\_\_\_\_  
 Date  
 312-775-8000  
 \_\_\_\_\_  
 Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1459, Alexandria, VA 22313-1459. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1459, Alexandria, VA 22313-1459.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

## **EXHIBIT 22**



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1459  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490

7590

10/25/2006

DONALD J. POCHAPIEN  
McANDREWS, HELD & MALLOY, LTD.  
CITICORP CENTER, 34TH FLOOR  
500 WEST MADISON STREET  
CHICAGO, IL 60661

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/782,594

Applicant(s)

BIANCHI ET AL.

Examiner

Paul B. Prebille

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.  
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-34, 61 and 62 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 26-34, 61 and 62 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB108)  
Paper No(s)/Mail Date 8/25/06

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date, \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### ***Claim Objections***

Claims 26, 28 objected to because of the following informalities:

In claim 26, on lines 5-8, "said bone graft and does not comprise an adhesive" is grammatically awkward because of "and." Also, "comprise" is confusing since it was used to end the preamble earlier in the claim. The Examiner suggest deleting "and (line 5) and replacing "comprise" (line 6) with ---include--- to overcome this objection.

In claim 28, the parentheses and quotation marks around "(“cortical bone pins”)" is not understood and it is unclear whether this language is limiting to the claim's scope. Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 79 of copending Application No. 09/941,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claim 79 is read on by

what is set forth in the claims of this application such claim 79 would be "anticipated" thereby. For this reason, the claims are considered obvious in view of claim 79; see *In re Goodman, supra*.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-27 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis (US 5,147,367), or in the alternative, under 35 U.S.C. 103(a) as being obvious over Ellis (US 5,147,367) alone. Ellis anticipates the claim language where the bone pieces or bone portions as claimed are the bone portions of the same patient grafted onto the bones they were separated from to form a graft in Ellis; see the

figures, the abstract and column 5, lines 12-56. "Graft" is denoted as "anything inserted into something else so as to become an integral part of the latter"; Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, p. 599. "Allograft" is a homograft (i.e. from the same species) that is allogenic (i.e. genetically distinct) to the recipient; see Merriam-Webster OnLine at [www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft](http://www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft). Since the bone of Ellis is capable of being used as a bone graft unit upon the death of the individual, it is considered an allograft bone portion with respect to another human being to the extent that this language can be given patentable weight. The site of source of the material is relative to how it can be used and is not indicative of the material itself because the pieces of Ellis are allogenic with respect to another human being. For these reasons, the separated bone pieces are grafts and allografts when these terms are given their broadest reasonable interpretation. The new claim language requiring "machined" bone portions is not structurally distinguishing from that disclosed by Ellis because it does require any particular structure in the device; see MPEP 2113 that is incorporated herein by reference.

Alternatively, Ellis could be interpreted as not meeting the claim language because one may interpret "machined" as implying a particular structure not disclosed by Ellis. However, since "machined" at most only may imply a slight difference from that of Ellis, the Examiner asserts that Ellis renders the claim language at least clearly obvious.

With regard to claim 27, the breaks or separations are in cortical bone because cortical bone is on the outside of bone as is visible in the drawings. The pins used are

inherently press-fitted into the holes formed because they are held there by a friction tight fit. Without this type of fit, they would not function properly.

With regard to claim 32, the pins of Ellis are cortical bone pins because they are for cortical bone the same way a "bone screw" is for bone even though it can be made of a metal.

Claims 26, 27, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al (US 5,716,358) in view of Ellis (US 5,147,367). Ochoa discloses bone portions or pieces grafted back onto bones they were separated from but fails to clearly disclose the use of a plurality of pins as now claimed; see Figures 4 and 5 as well as column 6, line 57 to column 8, line 47. However, Ellis teaches that it was known to use a plurality of pins to attach bone pieces together; see *supra*. Therefore, it is the Examiner's position that it would have been obvious to use a plurality of pins in the Ochoa invention in order to better secure the pieces together and for the same reasons that Ellis uses the same.

Claims s 26-34 and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation. Siebels also discloses that "the hollow space is filled with bone material or bone cement for the purpose of a radial anchoring of the ring"; see page 5 of the

translation. Also, on page 11 of the translation, Siebels discloses that "extraneous bone material, or the patient's own bone material" can be used to fill the cavity. However, Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6).

Coates, however, teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner's position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

Regarding claims 28-30, the spacers of Coates can have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Any segment thereof could be said to be made of cortical bone.

#### ***Response to Arguments***

Applicants' arguments filed August 25, 2006 have been fully considered but they are not persuasive in all cases.

Applicants failed to traverse the double patenting rejection and stated that they will address the provisional rejection once the application is otherwise allowable.

Applicants traverse the rejection utilizing Ellis by arguing that Ellis does not disclose a "graft" because the bone pieces are not from a different site or source. This has not been found persuasive because this argument is not based upon a structural difference, but rather, relies solely on where the material is obtained instead of a structural difference. In other words, the argument that the material of a graft is from a "different site or source" is not based upon the structure of the device, but rather, it is based upon the source of the material. Since the source of the material is not limiting in the context of the present claims, the argument is considered wholly unpersuasive.

Furthermore, the Examiner maintains that the broader definition applied is appropriate because there is no special definition for this term in the specification and because the broader definition is the broadest reasonable one available; the Examiner has included a copy of the definition from Stedman's Medical Dictionary utilized in the previous Office action.

Next, Applicants argue that the term "allograft" inherently means that the tissue has been chemically and physically processed into a non-living material that is said to be suitable for implantation. Although the art does process some allogenic materials for implantation, it is not inherent that all allografts are processed because there are clearly some allografts that are not processed; see, for example, US-20030077825 in paragraph [0024], US-20030036800 in paragraph [0007], and US-6,398,786 on column 1, lines 39-44 (see MPEP 2112.01 that is incorporated herein by reference). For this reason, the Examiner asserts that "allograft" merely indicates where the tissue is obtained and how it is intended to be used and not on any clear structural feature of the

material. Moreover, the whole transplant industry relies on living tissue grafts to provide the recipient with living tissue grafts. For these reasons, the rejections have been maintained.

With regard to the rejections utilizing Siebels and Coates, the Applicants' arguments follow the line of reasoning that it would not have been obvious to combine Siebels with Coates because Siebels wants easy assembly and Coates says that implants made of bone have been difficult to make.

In response, the Examiner asserts that Siebels desires easily assembleable disks that enable the surgeon to quickly assemble pre-manufactured disks into an appropriately sized implant. Coates, on the other hand, states that implants made with bone have had problems due primarily to their shapes and cancellous bone make-up. Coates discloses one example of a bone dowel that was not stable due to shape and cancellous bone make-up see the discussion of Cloward on column 3. Assembly of the implant pieces was not an issue. Coates solved the problems of the prior art by making the implant primarily of cortical bone and making the implant into a rectangular shape with vertebra engaging teeth and ridges to prevent migration. For this reason, the Examiner asserts that Coates is discussing an entirely different issue than that of Siebels. For this reason, the Applicants' line of reasoning is not persuasive.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3738

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Paul B. Prebilic  
Primary Examiner

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

**Complete If Known**

Application Number 08/782,594  
 Filing Date February 12, 2001  
 First Named Inventor Blanchi, John R.  
 Group Art Unit 3738  
 Examiner Name Paul B. Prebille  
 Attorney Docket Number RTI 112R/1915-13980US02

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Ward Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
PP	A1	5,192,327	03-09-1993	Brantigan	
	A2				
	A3				
	A4				
	A5				
	A6				
	A7				
	A8				
	A9				
	A10				
	A11				
	A12				

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	1 <sup>6</sup>
	A13					
	A14					
	A15					
	A16					
	A17					

**OTHER ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	A18	
	A19	
	A20	
	A21	
	A22	

EXAMINER SIGNATURE	/Paul Prebille/	DATE CONSIDERED	10/23/2006
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*Applicant's unique citation designation number (optional). \*See Kind Code of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. \*Easter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \*Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 37 U.S.C. 112 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form enter suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. Send TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Rev. Sept. 03

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<b>Notice of References Cited</b>	Application/Control No. 09/782,594	Applicant(s)/Patent Under Reexamination BIANCHI ET AL.	
	Examiner Paul B. Preblich	Art Unit 3738	Page 1 of 1

#### U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,985,788	01-2006	Paul et al.	623/17.11
*	B	US-2006/0106480	05-2006	Messerli et al.	623/017.11
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

#### FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

#### NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

## **EXHIBIT 23**

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:  
Bianchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"


Group Art Unit: 3738

Examiner: Paul B. Prebille

CERTIFICATE OF ELECTRONIC FILING

I hereby certify that this correspondence is  
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States Patent and Trademark Office on this  
date:

February 26, 2007

  
Jennifer Lacroix  
Registration No. 46,852  
Attorney for Applicants

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the final Office Action mailed October 25, 2006, Applicants respectfully request entry of the following amendments and a consideration of the response on the merits. This Amendment and Response is being filed with a Request for Continued Examination, and a One Month Petition for Extension of Time, and is therefore believed to be timely.

**Amendments to the Claims** begin on page 2 of this paper; and  
**Remarks/Arguments** begin on page 5 of this paper.

**Amendments to the Claims:**

Please substitute the listing of the claims as provided below for any prior listings:

Claims 1-25. (Canceled).

26. (Currently amended) An assembled bone graft, said assembled bone graft assembled outside the body and suitable for implantation into a human patient, said assembled bone graft comprising: a plurality of machined allograft bone portions layered to form a graft unit, and biocompatible pins comprising cortical bone traversing said graft unit for holding said graft unit together as an assembled bone graft, wherein said assembled bone graft ~~and does not include~~ comprise an adhesive.

27. (Currently Amended) An assembled bone graft suitable for implantation in a human patient comprising:

two distinct bone portions of cortical bone, and biocompatible pins comprising cortical bone, wherein said two distinct bone portions are machined allograft bone portions processed to be suitable for implantation in a human patient, said biocompatible pins are of appropriate diameter and press fitted into machined holes in said two bone portions to hold together said two bone portions to form an assembled bone graft suitable for implantation in humans.

28. (Currently Amended) An assembled bone graft suitable for implantation in a human patient comprising two or more distinct; bone portions of machined allograft bone and pins comprising cortical bone ("~~cortical bone pins~~"), said two or more distinct; bone portions having holes therein for receiving said ~~cortical bone~~ pins, said ~~cortical bone~~ pins keeping said two or more distinct; bone portions aligned and connected to form said assembled bone graft free of an adhesive and suitable for implantation in a human.

29. (Currently Amended) The assembled bone graft of claim 28 where there are two distinct; bone portions of machined allograft bone.

30. (Currently Amended) The assembled bone graft of claim 28, wherein said two or more distinct bone portions are selected from the group consisting of: cortical bone and cancellous bone.

31. (Previously Presented) An assembled bone graft suitable for implantation in a human patient, comprising:

a first machined bone portion having holes therein;

a second machined bone portion having holes therein aligned with the holes in said first bone portion, said first bone portion and said second bone portion being allograft bone suitable for implantation into a human patient; and

cortical bone pins press-fitted in said holes for holding said first bone portion in juxtaposition to said second bone portion and forming said assembled bone graft suitable for implantation into a human patient.

32. (Previously Presented) An assembled bone graft suitable for implantation in a human patient, comprising:

a first machined cortical bone portion having a hole therein;

a second machined cortical bone portion having a hole therein, said hole in said second machined cortical bone portion aligning with said hole in said first machined cortical bone portion, said first machined cortical bone portion and said second machined cortical bone portion being allograft bone suitable for implantation into a human patient;

a cortical bone pin press-fitted in the hole between said first cortical bone portion and said second cortical bone portion to form said assembled bone graft suitable for implantation into a human patient.

33. (Previously Presented) An assembled bone graft suitable for implantation into a human patient, comprising:

a first machined cortical bone portion having holes therein;

a second machined cortical bone portion having holes therein aligned with the holes in said first machined bone portion, said first machined cortical bone portion and said second machined cortical bone portion being allograft bone suitable for implantation into a human patient; and

cortical bone pins press-fitted in said holes for holding said first machined cortical bone portion in stacked juxtaposition to said second machined cortical bone portion and forming, without an adhesive, said assembled bone graft suitable for implantation into a human patient.

34. (Currently Amended) An assembled bone graft suitable for implantation into a human patient, comprising:

a first machined bone portion;

a second machined bone portion contacting said first machined bone portion to form a graft unit, said first machined bone portion and said second machined bone portion being allograft bone suitable for implantation into a human patient; and

~~biocompatible~~—pins comprising cortical bone inserted into said first machined bone portion and said second machined bone portion for holding together said graft unit to form said assembled bone graft suitable for implantation into a human patient.

Claims 35-60. (Canceled).

61. (Previously presented) The assembled implant of claim 31 wherein said cortical bone pins are four cortical bone pins, said cortical bone pins being made from cortical bone.

62. (Previously presented) The assembled implant of claim 33 wherein said cortical bone pins are four cortical bone pins, said cortical bone pins being made from cortical bone.

## REMARKS

### Status of the Claims

Claims 26-34 and 61-62 are currently pending.

Claim 26 is currently objected to based upon the use of "comprise" on lines 5-6. Claim 26 has been amended to recite "wherein said assembled bone graft does not include an adhesive." This amendment does not add new matter. Applicants believe that this amendment is grammatical in nature and does not change the scope of claim 26. Applicants believe that this amendment to claim 26 overcomes the currently pending objection. Claim 26 has also been amended to recite pins comprising cortical bone traversing said graft unit for holding said graft unit together as an assembled bone graft. This amendment does not add new matter.

Claims 27 and 34 have also been amended to recite pins comprising cortical bone. These amendments do not add new matter.

Claim 28 is currently objected to based upon the use of the term ("cortical bone pins"). Claim 28 has been amended to remove the parenthetical, and to recite, "An assembled bone graft suitable for implantation in a human patient comprising two or more distinct bone portions of machined allograft bone and pins comprising cortical bone, said two or more distinct bone portions having holes therein for receiving said pins, said pins keeping said two or more distinct bone portions aligned and connected to form said assembled bone graft free of an adhesive and suitable for implantation in a human." This amendment does not add new matter. Applicants believe that this amendment is grammatical in nature and does not change the scope of claim 28. Applicants believe that this amendment to claim 28 overcomes the currently pending objection.

Claims 29 and 30 have been amended to remove unnecessary commas between the words "distinct" and "bone." These amendments are grammatical in nature and do not alter the scope of the claims or add new matter to the claims.

Claims 26 and 33 are currently provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 79 of co-pending Application Serial No. 09/941,154. Applicants note this provisional rejection, and will take appropriate action if this rejection should ripen.

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Pat. No. 5,147,367 (the "Ellis" reference). Applicants respectfully traverse this rejection for the reasons stated in section I below.

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over the Ellis reference. Applicants respectfully traverse this rejection for the reasons stated in section II below.

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Pat. No. 5,716,358 (the "Ochoa" reference) in view of the Ellis reference. Applicants respectfully traverse this rejection for the reasons stated in section III below.

Claims 26-34 and 61-62 are currently rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 0517030 (the "Siebels" reference) in view of U.S. Pat. No. 5,989,289 (the "Coates" reference). Applicants respectfully traverse this rejection for the reasons stated in section IV below.

## **I. 35 U.S.C. § 102(B) OVER THE ELLIS REFERENCE**

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the Ellis reference (U.S. Pat. No. 5,147,367). With regard to the anticipation rejections, the MPEP provides:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

MPEP §2131 (emphasis added). Applicants respectfully traverse the current rejections under 35 U.S.C. §102(b) because the Ellis reference does not disclose each and every element of claims 26-27 and 31-34 of the instant application.

### **A. Ellis does not disclose a "graft" as the term is understood in the art**

Claims 26-27 and 31-34 are each directed to an "assembled bone graft." The Ellis reference does not teach a "graft" as the term is understood in the art. Tellingly, the Ellis

reference does not use the term "graft." Instead, the Ellis reference states that it relates to "fixation of bone fractures," (Ellis at Abstract), and the "setting of bone fragments relative to the adjacent bone mass." (Ellis at Col. 1, lines 6-8). The Ellis reference further describes this process as being a "repair." (Ellis at Col. 3, line 18; Col. 3, lines 41-42; Col. 5, line 13; and Col. 5, line 50). Figures 2a-2d and 3-5 of the Ellis reference further illustrate that Ellis relates to the fixation of bone fractures wherein a broken bone is re-attached to the same site from which it was fractured. (See Ellis at Figures 2a-2d and 3-5; see also Ellis at Col. 4, lines 16-18 ("FIG. 2a depicts a femur 20 which contains a fractured condyle 201 and an adjacent underlying bone mass 202.").)

In making the assertion that Ellis relates to "grafts," the Office Action disregards the teachings of Ellis as relating to bone repairs. Instead, the Office Action attempts to read "graft" into the Ellis reference by asserting that Ellis discloses a "graft" when the term "graft" is given its "broadest reasonable interpretation." See the October 25, 2006 Office Action at p. 4. In support of the interpretation of the term "graft," the October 25, 2006 Office Action cites to Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, p. 599, for the definition of "graft" as being "anything inserted into something else so as to become an integral part of the latter." See the October 25, 2006 Office Action at p. 4 (emphasis added). As discussed above, however, the Ellis reference relates to the fixation of bone fractures wherein a broken bone is re-attached to the same site from which it was fractured. The October 25, 2006 Office Action admits that Ellis discloses "bone portions of the same patient" being bound back "onto the bones they were separated from." See the October 25, 2006 Office Action at p. 3. This does not fit the definition of a graft as set forth in Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, at p. 599, because the bone fragments of Ellis are not being "inserted into something else."

Additionally, given the recognitions in the October 25, 2006 Office Action that Ellis discloses "bone portions of the same patient" being bound back "onto the bones they were separated from," see the October 25, 2006 Office Action at p. 3, the definition in Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, at p. 599 of "autogenous bone graft" as being "a bone [graft] from one part of the body to another" is particularly notable. In accordance with this definition, in order for a bone portion from a patient to be a "graft" with respect to that same patient, it would have to be taken from one part of the body and be put into another. The specification of the instant application is in accordance with this definition in referring

to autograft materials. See specification at p. 1, line 30 to p. 2, line 1 (“a second site of morbidity must be created to harvest autograft for implantation into a first diseased or injured site”).

The interpretation in the October 25, 2006 Office Action of a “graft” as including bone being re-attached to the site from which it was originally fractured is thus inconsistent with the term “graft” as used in the art, as evidenced by the fact that it is inconsistent with the definition in Stedman’s Medical Dictionary, 23<sup>rd</sup> Edition, at p. 599 that has been provided in the October 25, 2006 Office Action. “The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.” MPEP §2111.

#### **B. Ellis Does Not Disclose An “Assembled Bone Graft”**

Claims 26-27 and 31-34 are each directed to an “assembled bone graft.” The Ellis reference does not disclose an assembled bone graft as recited in any of these claims. As discussed above, the Ellis reference does not disclose a “graft.” Additionally, each of claims 26-27 and 31-34 recites elements relating to the “assembled bone graft” recited therein that are not met by the Ellis reference.

Claim 26 recites, among other things, that the assembled bone graft comprises “a plurality of machined allograft bone portions layered to form a graft unit, and biocompatible pins traversing said graft unit for holding said graft unit together as an assembled bone graft.” Claim 26 also recites that the assembled bone graft is “assembled outside the body and suitable for implantation into a human patient.” The Ellis reference discloses neither of these elements. For example, in the Ellis reference only a single bone portion is shown as being broken or fractured, and being subsequently fixed to the underlying bone mass. (See Ellis at Col. 2, lines 56-64; Col. 3, lines 3-5; Col. 3, lines 19-22; Col. 3, lines 28-34; Col. 3, lines 38-40; Col. 4, lines 16-18; Col. 4, lines 27-28; Col. 5, lines 41-42; and at Figs. 2a-2d and 3-5.) As disclosed in Ellis, the single fractured fragment is fixed to the underlying bone mass to re-form the original bone inside the body. The Ellis reference does not disclose removing the fractured or broken bone from the body. The broken or fractured bone as disclosed in Ellis thus does not exist in an “assembled”

form outside the body as an “assembled bone graft” that is “suitable for implantation into a human patient.”

Similarly, claims 27 and 31-34 each require an “assembled bone graft” comprising “two distinct bone portions” (claim 27), or “a first” and “a second” bone portion (claims 31-34), that form “an assembled bone graft suitable for implantation” into a human patient. As discussed above, the Ellis reference does not disclose an assembled bone graft comprising two bone portions that are implanted into a human patient. Instead, the Ellis reference discloses a single bone being broken or fractured from the underlying bone mass, and being subsequently fixed to the underlying bone mass. (See Ellis at Col. 2, lines 56-64; Col. 3, lines 3-5; Col. 3, lines 19-22; Col. 3, lines 28-34; Col. 3, lines 38-40; Col. 4, lines 16-18; Col. 4, lines 27-28; Col. 5, lines 41-42; and at Figs. 2a-2d and 3-5.)

#### **C. Ellis Does Not Disclose “Allograft” Bone**

The October 25, 2006 Office Action states that “Ellis anticipates the claim language where the bone pieces or bone portions of the same patient are grafted back onto the bones they were separated from to form a graft in Ellis....” See the October 25, 2006 Office Action at pp. 3-4. Although applicants disagree with the characterization of the Ellis reference as relating to a “graft” at all, as discussed above, the admission that Ellis relates to “bone portions of the same patient” is an admission that the claimed element of “allograft bone” is not disclosed in Ellis.

The October 25, 2006 Office Action asserts that “[s]ince the bone of Ellis is capable of being used as a bone graft unit upon the death of the individual, it is considered an allograft bone portion....” See the October 25, 2006 Office Action at p. 4. The Ellis reference, however, does not disclose, either explicitly or inherently, that the bone disclosed therein could or should be used in another patient upon the death of the first patient. Instead, the assertion in the October 25, 2006 Office Action is based solely upon presumption, with no teaching in the art cited as support. The assertion set forth in the October 25, 2006 Office Action does not constitute a description of the claim element being set forth in the cited reference, as is required for anticipation by MPEP §2131. The Ellis reference therefore does

not anticipate the claim element of "allograft bone" as recited in each of claims 26-27 and 31-34.

The October 25, 2006 Office Action also asserts that the claim elements reciting allograft bone "merely indicate[] where the tissue is obtained and how it is intended to be used and not on any clear structural feature of the material." October 25, 2006 Office Action at pp. 7-8. Applicants respectfully disagree with this characterization of the claim element "allograft." The requirement that bone be allograft is a positively recited requirement within the body of the claim, and is not merely a statement of intended use. The claim element requiring allograft bone cannot be ignored.

#### **D. Ellis Does Not Disclose a "Machined" Portion of Bone**

Claims 26-27 and 31-34 each recite as an element that the bone portions of the assembled bone graft are "machined." As discussed above, the Ellis reference discloses repairing a bone break or fracture by reattaching a single fractured piece of bone to the "adjacent underlying bone mass" from which it originally fractured. See Ellis at Col. 4, lines 16-18 ("FIG. 2a depicts a femur 20 which contains a fractured condyle 201 and an adjacent underlying bone mass 202"). The Ellis reference does not disclose machining a bone portion. The claim elements in claims 26-27 and 31-34 reciting "machined" bone portions are thus not anticipated by the Ellis reference.

Because there are numerous claim elements in each of claims 26-27 and 31-34 that are not disclosed in the Ellis reference, the Ellis reference does not anticipate any of claims 26-27 or 31-34. Applicants respectfully request that the pending rejection under 35 U.S.C. §102(b) in light of the Ellis reference be withdrawn.

## **II. 35 U.S.C. § 103(A) IN LIGHT OF ELLIS**

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over the Ellis reference. In order for a prima facie case of obviousness to be established, the Manual of Patent Examining Procedure (MPEP) states:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the teaching. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art.

MPEP §2142 (emphasis added). "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness." See id.

Applicants respectfully submit that no prima facie case of obviousness has been established because the cited reference does not teach or suggest each of the elements of any of claims 26-27 or 31-34. Additionally, as discussed above, the Ellis reference relates to the repair of fractured or broken bones within a patient. For example, the Ellis reference does not disclose an assembled bone graft suitable for implantation into a human patient that comprises multiple bone portions. As another example, the Ellis reference also does not disclose the use of machined allograft bone portions in forming an assembled bone graft. Modification of the teachings of Ellis to arrive at such subject matter would change the principle of operation of the cited reference, which is not sufficient to render the claims prima facie obvious. See MPEP §2143.01 (citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)).

Applicants respectfully request that the pending rejection under 35 U.S.C. §103(a) in light of the Ellis reference be withdrawn.

## **III. 35 U.S.C. § 103(A) OVER OCHOA IN VIEW OF ELLIS**

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Pat. No. 5,716,358 (the "Ochoa" reference) in view of the Ellis reference. The October 25, 2006 Office Action states that "Ochoa discloses bone portions or pieces grafted back onto bones they were separated from but fails to clearly disclose the use

of a plurality of pins as now claimed.” See October 25, 2006 Office Action at p. 5. The Office Action then cites to Ellis for the proposition that “it was known to use a plurality of pins to attach bone pieces together.” See October 25, 2006 Office Action at p. 5.

The October 25, 2006 Office Action does not show the manner by which each and every element of any of the currently amended claims is allegedly met by the cited references, either alone or in combination. “The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness,” MPEP §2142, and part of that burden includes establishing that the prior art references teach or suggest all the claim limitations.

The Applicants respectfully submit that the cited combination of Ellis and Ochoa fails to make a *prima facie* case of obviousness against the presently claimed invention because the combination of the two references fails to disclose each and every element of the currently amended claims. The Ochoa reference is directed to a “bone fixation device such as a screw, pin, staple, cable, or anchor.” See the Ochoa reference at Abstract. The Ochoa reference further states that “[t]he present invention relates to mechanical fixation devices and hardware used in surgical applications to attach or anchor bone tissue or prosthetic devices to bone, or to secure pieces of bone together.” See the Ochoa reference at Col. 1, lines 4-7. Ochoa, like Ellis, does not disclose assembled bone grafts such as those recited in claims 26-26 and 31-34.

For example, each of claims 26-27 and 31-34 are directed to an “assembled bone graft” that is “suitable for implantation” in a human patient, where the assembled bone graft comprises a plurality of bone portions. The Ochoa reference discloses that the fixation device disclosed therein can be used to reconstruct broken bones within a patient by threading a plurality of bone fragments together, (see the Ochoa reference at col. 6, lines 58-60), but as indicated in the October 25, 2006 Office Action, this relates to “bone portions or pieces grafted back onto bones they were separated from.” See October 25, 2006 Office Action at p. 5. Ochoa does not teach a bone graft that is assembled from multiple bone portions and then implanted into a patient, as is required by each of claims 26-27 and 31-34. Because Ellis also does not teach such assembled bone grafts, the combination of Ellis and Ochoa does not render the currently amended claims obvious.

Additionally, each of claims 26-27 and 31-34 recite that the bone portions used in the assembled grafts are machined allograft bone. Ochoa and Ellis are directed to repairing

fractured bones within a patient. Neither reference disclose either the use of machined bone portions or the use of allograft bone, much less the use of bone that is both machined and allograft.

In light of the fact that each and every limitation of the currently amended claims is not disclosed or taught by Ochoa or Ellis, Applicants respectfully request that the pending rejection under 35 U.S.C. §103(a) in light of Ochoa and Ellis withdrawn.

#### **IV. 35 U.S.C. § 103(A) OVER SIEBELS IN VIEW OF COATES**

Claims 26-34 and 61-62 are currently rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 0517030 (the "Siebels" reference) in view of U.S. Pat. No. 5,989,289 (the "Coates" reference). The October 25, 2006 Office Action asserts that "Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together by aligning bones of adjacent pieces," and introducing "pins into the aligned bones to hold the implant pieces together." See the October 25, 2006 Office Action at p. 5. The October 25, 2006 Office Action admits that "Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6)." See the October 25, 2006 Office Action at p. 5. The October 25, 2006 Office Action then cites to Coates, alleging that Coates "teaches that it was well known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61." See the October 25, 2006 Office Action at p. 6. The October 25, 2006 Office Action then concludes that "it would have been obvious to make the discs and pins of Siebels implant out of cortical bone for the same reasons the [sic] Coates teaches doing the same." See the October 25, 2006 Office Action at p. 6. The Applicants respectfully traverse this rejection, and submit that it would not have been obvious to one of ordinary skill in the art to combine the teachings of Siebels and Coates to arrive at the currently claimed subject matter.

A person of ordinary skill in the art would not have combined the teachings of Siebels and Coates because they relate to different approaches to making implants. There would not be a reasonable expectation of success in making the combination proposed by

the October 25, 2006 Office Action. An obviousness rejection must include "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, (Federal Circuit 2006).

When the substance and teachings of the Siebels reference and the Coates reference are properly considered, it is clear that one of ordinary skill in the art would not be motivated to combine the two references by replacing the artificial materials used in Siebels with the cortical bone used in the implants of Coates. It is not permissible to pick and choose among the individual elements of assorted prior art references to re-create the claimed invention, but rather "some teaching or suggestion in the references to support their use in the particular claimed combination" is needed. Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1576, 19 USPQ2d 1241, 1246 (Fed. Cir. 1991). Furthermore, prior art references must be considered in their entirety, "i.e., as a whole, including portions that would lead away from the claimed invention." MPEP at § 2141.02. (Emphasis added.)

**A. A Person of Ordinary Skill in the Art Would Not Have Modified Siebels to Substitute Bone for Plastic**

The Siebels reference describes the basis of the invention described therein in the following manner:

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which – from the standpoint of manufacturing engineering – can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.

See Siebels translation at p. 2. Ease of manufacturing and ease of implantation are central aspects of the Siebels implant, and serve as the solutions for the nature of the problem addressed by Siebels. To achieve the aspect of "ease" of manufacturing, Siebels relies upon cutting disks out of a "prefabricated solid or hollow strand." See Siebels translation at p. 3.

The only materials actually described in the Siebels reference from which the disks and/or anchoring pins described therein can be made are "fiber reinforced plastic," see Siebels translation at p. 3, and "carbon-fiber reinforced plastic." See Siebels translation at

p. 6. The Siebels reference does not describe any other materials from which its implants or anchoring pins can be made.

With respect to the anchoring pins disclosed in the Siebels reference, there is no discussion, aside from the one reference to carbon-fiber reinforced plastic on page 6, of suitable materials from which they can be made. Nor is there any discussion of the parameters or factors that should be considered when choosing the material from which to make the anchoring pins. There is thus no teaching within the Siebels reference to guide one of ordinary skill in the art in choosing any material for the anchoring pins other than carbon-fiber reinforced plastic.

With respect to the disks used for the implants described in the Siebels reference, the manufacturing methods by which the implants of Siebels can "easily be manufactured" in accordance with the "basis of the [proposed] invention," see Siebels translation at p. 2, make it evident that the only suitable materials are the plastics described therein. For example, the manufacturing techniques of Siebels are described in the following manner:

Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ["washers"] can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.

Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages [packings] can be designed.

Siebels translation at pp. 6-7 (emphasis added). Additionally, the Siebels reference describes one embodiment by explaining that:

The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in

order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having a rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.

Siebels translation at pp. 3-4 (emphasis added). Furthermore, Figures 5 and 6 of the Siebels reference provide illustrations of the manufacturing of the winding methods described in Siebels and the disks cut therefrom. The structure and shape of the disks described by Siebels are dictated by the braided or wound stands from which they are cut, and even the strength and rigidity of the disks is a result of the oriented fibers that result from the manufacturing techniques. The manufacturing methods taught in the Siebels reference that achieve the described advantages may be suitable for use with the plastics described in Siebels, but they could not be performed on cortical bone.

The Siebels reference, when read as a whole, is directed to providing implants and implant components that can be easily manufactured. The Siebels reference thus teaches away from the use of materials or manufacturing techniques that do not provide the benefit of easy manufacturing as described within the Siebels reference. There is no teaching or suggestion in Siebels that the manufacturing techniques could be altered or disregarded in making the disks taught therein.

The MPEP explains that "[a] prior art reference that 'teaches away' from the claimed invention is a significant factor to be considered in determining obviousness." MPEP §2145(X)(D)(1). Further, "[a] prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant.'" Monarch Knitting v. Sulzer, 139 F.3d 877, 885, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998). In reading the Siebels reference, one of ordinary skill would be led towards the ease of manufacturing obtained by using the plastics and manufacturing methods described in Siebels and would therefore be led in a divergent

direction from developing different manufacturing techniques to allow the use of bone as a manufacturing material.

**B. Coates Does Not Teach that Bone Can Be Substituted For The Materials of Siebels**

The Coates reference, when considered as a whole, does not teach that cortical bone could be used in the implants of Siebels.

As an initial matter, the implants disclosed in the Coates reference differ from the implants and portions of implants claimed in the present application in several respects. As described in Coates, "[t]he spacer 110 includes an anterior wall 111 having opposite ends 112, 113, a posterior wall 115 having opposite ends 116, 117 and two lateral walls 120, 121. Each of the lateral walls 120, 121 is connected between the opposite ends 112, 113, 116, 117 of the anterior 111 and posterior 115 walls to define a chamber 130. The walls are each composed of a bone composition, preferably cortical bone." See Coates at Col. 5, ln 66 to Col. 6, ln 5. In contrast to the assembled bone grafts recited in claims 26-34 and 61-62, the Coates reference does not describe bone grafts made from multiple pieces of cortical bone, nor does it describe connecting multiple pieces of bone using pins made from cortical bone.

Coates seeks to develop implants made of bone that "avoid the disadvantages of metal implants." See Coates at Col. 2, lns 50-51. In describing the benefits of its implants, the Coates reference states:

One benefit of the spacers of the present invention is that they combine the advantages of bone grafts with the advantages of metals, without the corresponding disadvantages. An additional benefit is that the invention provides a stable scaffold for bone ingrowth before fusion occurs. Still another benefit of this invention is that it allows the use of bone grafts without the need for metal cages or internal fixation, due to the compressive strength of the spacer and the means for resisting migration.

See Coates at Col. 4, lns 8-16. (Emphasis added).

Notably, the Coates reference does not discuss plastic implants, or the advantages or disadvantages thereof as compared to either metal or bone implants. The Coates reference does not provide any teaching with respect to the possibility or desirability of

substituting the use of bone in other grafts, such as those of the Siebels reference, that are made from plastic. With respect to materials and manufacturing methods, the Coates reference provides the following description:

The spacers of this invention are preferably formed of a bone composition or material. The bone may be autograft, allograft, xenograft or any of the above prepared in a variety of ways. Cortical bone is preferred for its compressive strength. In one embodiment, the spacers are obtained as a cross sectional slice of a shaft of a long bone. For example, various shaped spacers may be obtained by machining a cortical ring into the desired configuration. The exterior surfaces of the walls can be formed by machining the ring to a D-shape. Material from the medullary canal of the ring can be removed to form a chamber. Surface features and migration resistance means can be defined into the surface of the spacers using conventional machining methods and a standard milling machine which have been adapted to bone. Various methods and procedures are known for treating and processing bone to provide bone materials and compositions. These methods and procedures can be applied to the present invention as long as the resulting bone material provides a sufficient compressive strength for the intended application.

See Coates at Col. 11, lns 42-60. (Emphasis added). Thus, the known methods of manufacturing described in Coates require modifications in order to adapt the equipment for use with bone. Further, in the Background section provided therein, the Coates reference discusses some of the disadvantages and difficulties that were known with respect to making implants from bone:

Both allograft and autograft present additional difficulties. Graft alone may not provide the stability required to withstand spinal loads. Internal fixation can address this problem but presents its own disadvantages such as the need for more complex surgery as well as the disadvantages of metal fixation devices. Also, the surgeon is often required to repeatedly trim the graft material to obtain the correct size to fill and stabilize the disc space. This trial and error approach increases the length of time required for surgery. Furthermore, the graft material usually has a smooth surface which does not provide a good friction fit between the adjacent vertebrae. Migration and expulsion of the graft may cause neural and vascular injury, as well as collapse of the disc space. Even where such slippage does not occur, micromotion at the graft/fusion-site interface may disrupt the healing process that is required for fusion.

Several attempts have been made to develop a bone graft substitute which avoids the disadvantages of metal implants and bone grafts while capturing advantages of both. In each case, developing an implant having the

biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been extremely difficult or impossible.

See Coates at Col. 3, lns 17-40. (Emphasis added). Thus, it was considered "extremely difficult or impossible" to provide an implant that had the benefits of both bone and metal without their undesired properties. And, although the Coates reference goes on to describe its single piece bone implants as providing one solution to the difficulties associated with using bone implants, the Coates reference when read as a whole does not provide a teaching that bone can simply be substituted as a manufacturing material in any type of implant.

In light of the disclosures of the Siebels reference and the Coates reference when read in their entirety, one of ordinary skill in the art would not combine the Siebels reference and the Coates reference to arrive at implants or portions of implants made from multiple pieces of cortical bone connected by cortical bone pins as disclosed and claimed in the present application. "A critical step in analyzing the patentability of claims pursuant to Section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." *In re Kotzab*, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000); see also *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). When this critical step is taken with respect to the Siebels reference and the Coates reference, it becomes apparent that given the "extremely difficult or impossible" setting of developing an implant from cortical bone as described in the Coates reference, one skilled in the art would not have substituted cortical bone of Coates for the "extraordinarily easy" to use braided or wound plastics of Siebels. The teachings of Coates thus fail to address or overcome the stated manufacturing advantages associated with the fiber reinforced plastic of Siebels, so one of ordinary skill in the art would not have disregarded the ease of manufacturing advantages associated with the plastics of Siebels in choosing the materials for making either the primary components of an implant or the pins used to hold the implant together. Moreover, given the art recognized extreme difficulty or impossibility of developing an implant made from a single piece of cortical bone as disclosed in Coates, it would not have been obvious to one of ordinary skill in the

art to further modify the implants of Coates by building an implant assembled from pieces of cortical bone held together with pins.

**C. There is No Reasonable Expectation of Success in Combining Siebels and Coates**

The October 25, 2006 Office Action does not provide any basis for a reasonable expectation of success for using cortical bone to manufacture implants and portions of implants made from multiple pieces held in juxtaposition by cortical bone pins, as described and claimed in the present application. When addressing the issue of a reasonable expectation of success, the MPEP explains, "Obviousness does not require absolute predictability, however, at least some degree of predictability is required." MPEP §2143.02. The MPEP further states, "Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made." MPEP §2143.02. When the cited prior art references are viewed in this context, it becomes apparent that they do not provide a reasonable expectation of success with respect to substituting cortical bone as a manufacturing material into the implant pieces of the Siebels reference. For example, given the difficulties with making bone grafts as described in the Coates reference, there would not have been a reasonable expectation of success that implants could be assembled from multiple pieces of cortical bone. The Coates reference is directed to a single piece implant and does not address the utilization of multiple pieces.

Further, both the Coates reference and the Siebels reference discuss the need for implant strength, but neither addresses whether multiple cortical bone pieces held in juxtaposition would provide such strength. To the contrary, the Coates reference expresses the concern that "[g]raft alone may not provide the stability required to withstand spinal loads," see Coates at Col. 3, lns 18-19, and then states that "the spacers of this invention stimulate bone ingrowth like a bone graft and provide sufficient strength to support the vertebral column but avoid the disadvantages of both bone graft and metal implants...." See Coates at Col. 5, lns 21-24 (Emphasis added). Similarly, the Siebels reference describes that the fiber reinforced plastic implants disclosed therein "are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation

equally imparts an optimal rigidity and strength to the implant." See Siebels translation at p. 3 (emphasis added). Thus, while the Coates and Siebels references each describe that their own implants provide the necessary strength, neither one provides a basis from which it could be concluded that cortical bone pieces held in juxtaposition by cortical bone pins would successfully provide sufficient strength.

Because the combination of references in the pending obviousness rejection is not based upon any reasonable expectation of success found in the prior art, a prima facie case of obviousness has not been made and the rejection should be withdrawn.

### Conclusion

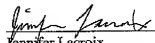
Claims 26-34 and 61-62 are currently pending. The specification currently stands objected. Claims 26-34 and 61-62 currently stand rejected. In view of the amendments and arguments provided herein, Applicants believe that all bases for objecting to and rejecting claims 26-34 and 61-62 have been overcome. Applicants respectfully submit that Claims 26-34 and 61-62 of the instant application are in a condition for allowance.

Applicants believe that a total fee of \$910 is currently due in conjunction with submission, with \$790 for the Request for Continued Examination and \$120 for the One Month Petition for Extension of Time that are being submitted with this Amendment and Response. The Commissioner is hereby further authorized to charge any fees which may be required, or credit any overpayment, to Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Respectfully submitted,

Date: February 26, 2007

By:

  
Jennifer Lacroix  
Attorney for Applicants  
Registration No. 46,852

McAndrews, Held & Malloy, Ltd.  
500 W. Madison St.  
34<sup>th</sup> Floor  
Chicago, IL 60661  
Phone: 312-775-8000  
Fax: 312-775-8100

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	09782594			
<b>Filing Date:</b>	12-Feb-2001			
<b>Title of Invention:</b>	Assembled implant			
<b>First Named Inventor/Applicant Name:</b>	John R. Bianchi			
<b>Filer:</b>	Jennifer Elizabeth Lacroix/Grace LaSota			
<b>Attorney Docket Number:</b>	RTI- 112R			
Filed as Large Entity				
<b>Utility      Filing Fees</b>				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				
<b>Extension-of-Time:</b>				
Extension - 1 month with \$0 paid	1251	1	120	120

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Miscellaneous:</b>				
Request for continued examination	1801	1	790	790
<b>Total in USD (\$)</b>				<b>910</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	1544789
<b>Application Number:</b>	09782594
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	9490
<b>Title of Invention:</b>	Assembled Implant
<b>First Named Inventor/Applicant Name:</b>	John R. Bianchi
<b>Correspondence Address:</b>	DONALD J. POCHOPIEN McANDREWS, HELD & MALLOY, LTD. CITICORP CENTER, 34TH FLOOR 500 WEST MADISON STREET CHICAGO IL 60661 US 4072280329 -
<b>Filer:</b>	Jennifer Elizabeth Lacroix/Grace LaSota
<b>Filer Authorized By:</b>	Jennifer Elizabeth Lacroix
<b>Attorney Docket Number:</b>	RTI- 112R
<b>Receipt Date:</b>	26-FEB-2007
<b>Filing Date:</b>	12-FEB-2001
<b>Time Stamp:</b>	16:40:46
<b>Application Type:</b>	Utility

### Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	\$ 910
RAM confirmation Number	583

Deposit Account	130017
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	13980US02-RCE-transmittal.pdf	641122	no	3
Warnings:					
Information:					
2		13980US02RCEwithAmendmentandExtension.pdf	1147604	yes	22
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Extension of Time		1	1	
	Amendment After Final		2	2	
	Claims		3	5	
	Applicant Arguments/Remarks Made in an Amendment		6	22	
Warnings:					
Information:					
3	Fee Worksheet (PTO-06)	fee-Info.pdf	8295	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1797021		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

# **REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL** **(Submitted Only via EFS-Web)**

Application Number	09/782,594	Filing Date	2001-02-12	Docket Number (if applicable)	13980US02	Art Unit	3738
First Named Inventor	John R. Bianchi			Examiner Name	Paul B. Prebilio		

**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

## **SUBMISSION REQUIRED UNDER 37 CFR 1.114**

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on \_\_\_\_\_

☐ Other \_\_\_\_\_

☒ Enclosed

☒ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other \_\_\_\_\_

## **MISCELLANEOUS**

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months \_\_\_\_\_  
 (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other \_\_\_\_\_

## **FEEs**

☐ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**  
 The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No \_\_\_\_\_

## **SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**

☒ Patent Practitioner Signature

☐ Applicant Signature

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Jennifer E. Lacroix/	Date (YYYY-MM-DD)	2007-02-26
Name	Jennifer E. Lacroix	Registration Number	46852

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

<b>PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)</b> <b>FY 2005</b> <i>(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818))</i>		Docket Number (Optional) 13880US02
Application Number 09/782,594		Filed February 12, 2001
For Assembled Implant		
Art Unit 3738		Examiner Paul B. Preblich

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.


The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

- |   | <u>Fee</u> | <u>Small Entity Fee</u> |
|---|------------|-------------------------|
| <input checked="" type="checkbox"/> One month (37 CFR 1.17(a)(1)) | \$120      | \$60 <u>\$120.00</u>    |
| <input type="checkbox"/> Two months (37 CFR 1.17(a)(2))           | \$450      | \$225 <u>\$</u>         |
| <input type="checkbox"/> Three months (37 CFR 1.17(a)(3))         | \$1020     | \$510 <u>\$</u>         |
| <input type="checkbox"/> Four months (37 CFR 1.17(a)(4))          | \$1590     | \$795 <u>\$</u>         |
| <input type="checkbox"/> Five months (37 CFR 1.17(a)(5))          | \$2160     | \$1080 <u>\$</u>        |
- ☐ Applicant claims small entity status. See 37 CFR 1.27.
- ☐ A check in the amount of the fee is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director has already been authorized to charge fees in this application to a Deposit Account.
- ☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 13-0017. I have enclosed a duplicate copy of this sheet.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

- I am the ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71  
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).
- ☒ attorney or agent of record. Registration Number 46,852
- ☐ attorney or agent under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34. \_\_\_\_\_

 _____ Signature Jennifer E. Lacroix	February 26, 2007 _____ Date 312-775-8000 _____ Telephone Number
Typed or printed name	

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

- ☐ Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.  
If you need assistance in completing the form, call 1-800-PTO-9193 and select option 2.

## **EXHIBIT 24**



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490
7590 05/03/2007				
DONALD J. POCHAPIEN McANDREWS, HELD & MALLOY, LTD. CITICORP CENTER, 34TH FLOOR 500 WEST MADISON STREET CHICAGO, IL 60661				
EXAMINER				
PREBILIC, PAUL B				
ART UNIT		PAPER NUMBER		
3738				
MAIL DATE		DELIVERY MODE		
05/03/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/782,594

Applicant(s)

BIANCHI ET AL.

Examiner

Paul B. Prebille

Art Unit

3738

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-34, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-34, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2007 has been entered.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 79 of copending Application No. 09/941,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claim 79 is read on by what is set forth in the claims of this application such claim 79 would be "anticipated"

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thereby. For this reason, the claims are considered obvious in view of claim 79; see *In re Goodman, supra*.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis (US 5,147,367), or in the alternative, under 35 U.S.C. 103(a) as being obvious over Ellis (US 5,147,367) alone. Ellis anticipates the claim language where the bone pieces or bone portions as claimed are the bone portions of the same patient grafted onto the bones they were separated from to form a graft in Ellis; see the figures, the abstract and column 5, lines 12-56. "Graft" is denoted as "anything inserted into something else so

as to become an integral part of the latter"; Stedman's Medical Dictionary, 23<sup>rd</sup> Edition, p. 599. "Allograft" is a homograft (i.e. from the same species) that is allogenic (i.e. genetically distinct) to the recipient; see Merriam-Webster OnLine at [www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft](http://www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft). Since the bone of Ellis is capable of being used as a bone graft unit upon the death of the individual, it is considered an allograft bone portion with respect to another human being to the extent that this language can be given patentable weight. The site of source of the material is relative to how it can be used and is not indicative of the material itself because the pieces of Ellis are allogenic with respect to another human being. For these reasons, the separated bone pieces are grafts and allografts when these terms are given their broadest reasonable interpretation. The new claim language requiring "machined" bone portions is not structurally distinguishing from that disclosed by Ellis because it does require any particular structure in the device; see MPEP 2113 that is incorporated herein by reference.

Alternatively, Ellis could be interpreted as not meeting the claim language because one may interpret "machined" as implying a particular structure not disclosed by Ellis. However, since "machined" at most only may imply a slight difference from that of Ellis, the Examiner asserts that Ellis renders the claim language at least clearly obvious.

With regard to claim 32, the pins of Ellis are cortical bone pins because they are for cortical bone the same way a "bone screw" is for bone even though it can be made of a metal.

Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al (US 5,716,358) in view of Ellis (US 5,147,367). Ochoa discloses bone portions or pieces grafted back onto bones they were separated from but fails to clearly disclose the use of a plurality of pins as now claimed; see Figures 4 and 5 as well as column 6, line 57 to column 8, line 47. However, Ellis teaches that it was known to use a plurality of pins to attach bone pieces together; see *supra*. Therefore, it is the Examiner's position that it would have been obvious to use a plurality of pins in the Ochoa invention in order to better secure the pieces together and for the same reasons that Ellis uses the same.

Claims 26-34 and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation. Siebels also discloses that "the hollow space is filled with bone material or bone cement for the purpose of a radial anchoring of the ring"; see page 5 of the translation. Also, on page 11 of the translation, Siebels discloses that "extraneous bone material, or the patient's own bone material" can be used to fill the cavity. However, Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6).

Coates, however, teaches that is was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner's position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

Regarding claims 28-30, the spacers of Coates can have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Any segment thereof could be said to be made of cortical bone.

#### ***Response to Arguments***

Applicants' arguments filed February 26, 2007 have been fully considered but they are not persuasive in all cases.

Applicants failed to traverse the double patenting rejection and stated that they will address the provisional rejection once the application is otherwise allowable.

Applicants traverse the rejection utilizing Ellis by arguing that Ellis does not disclose a "graft" because the bone pieces are not supposed utilized by the Examiner in a way that is "understood by the art." Rather, the Applicant understands the term as meaning that the material must be from a different site or source. This has not been found persuasive because this argument is not based upon a structural difference, but rather, relies solely on where the material is obtained instead of a structural difference.

In other words, the argument that the term "graft" is not used to describe his material is not persuasive. Furthermore, the fact that the Ellis does disclose that the material is not from a different site or source is not based upon the structure of the device, but rather, it is based upon the source of the material. Since the source of the material is not limiting in the context of the present claims, the argument is considered wholly unpersuasive.

Furthermore, the Examiner maintains that the broader definition applied is appropriate because there is no special definition for this term in the specification and because the broader definition is the broadest reasonable one available; the Examiner has included a copy of the definition from Stedman's Medical Dictionary utilized in the previous Office action.

Next, Applicants argue that the term "allograft" inherently means that the tissue has been chemically and physically processed into a non-living material that is said to be suitable for implantation. Although the art does process some allogenic materials for implantation, it is not inherent that all allografts are processed because there are clearly some allografts that are not processed; see, for example, US-20030077825 in paragraph [0024], US-20030036800 in paragraph [0007], and US-6,398,786 on column 1, lines 39-44 (see MPEP 2112.01 that is incorporated herein by reference). For this reason, the Examiner asserts that "allograft" merely indicates where the tissue is obtained and how it is intended to be used and not on any clear structural feature of the material. Moreover, the whole transplant industry relies on living tissue grafts to provide

the recipient with living tissue grafts. For these reasons, the rejections have been maintained.

On page 8 of the February 26, 2007 response, the Applicants argue that Ellis does not disclose an assembled bone graft. However, it is noted that this terminology is taken from the preamble and that the preamble is not incorporated into the body of the claims. For this reason, the preamble is merely considered to be a statement of intended use and it does not structurally limit the claim language.

On page 10 of the response, the Applicants argue that Ellis does not disclose machined portions of bone. However, the Examiner asserts that this language is not clearly limiting because even a kick on the bone would constitute a machining. Furthermore, since the bone joined by a fastener, it is machined to accommodate the fastener to the extent that this term can be given patentable weight.

With regard to the rejections utilizing Siebels and Coates, the Applicants' arguments follow the line of reasoning that it would not have been obvious to combine Siebels with Coates because Siebels wants easy assembly and Coates says that implants made of bone have been difficult to make.

In response, the Examiner asserts that Siebels desires easily assembleable disks that enable the surgeon to quickly assemble pre-manufactured disks into an appropriately sized implant. Coates, on the other hand, states that implants made with bone have had problems due primarily to their shapes and cancellous bone make-up. Coates discloses one example of a bone dowel that was not stable due to shape and cancellous bone make-up see the discussion of Cloward on column 3. Assembly of the

Art Unit: 3738

implant pieces was not an issue. Coates solved the problems of the prior art by making the implant primarily of cortical bone and making the implant into a rectangular shape with vertebra engaging teeth and ridges to prevent migration. For this reason, the Examiner asserts that Coates is discussing an entirely different issue than that of Siebels. For this reason, the Applicants' line of reasoning is not persuasive.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 3738

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilitic  
Primary Examiner  
Art Unit 3738

# **Notice of References Cited**

Application/Control No.

09/782,594

Applicant(s)/Patent Under  
Reexamination  
BIANCHI ET AL.

Examiner

Paul B. Preblich

Art Unit

3738

Page 1 of 1

## **U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2006/0241763	10-2006	Paul et al.	623/017.11
*	B	US-2007/0016295	01-2007	Boyd, Lawrence M.	623/017.11
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

## **FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

## **NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a))  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

## **EXHIBIT 25**

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:

Bianchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

Group Art Unit: 3738

Examiner: Paul B. Prebille

) Certificate of Electronic Transmission

) I hereby certify that this correspondence is  
) being transmitted electronically to the U.S.  
) Patent and Trademark Office via EFS on:

) November 5, 2007

) /Sarah A. Kofflin/

) Sarah A. Kofflin

) Registration No. 60,218

) Customer No. 23,446

AMENDMENT AND REQUEST FOR CONSIDERATION

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the non-final Office Action mailed May 3, 2007, Applicants respectfully request entry of the following amendments and a consideration of the response on the merits. This Amendment and Response is believed to be timely because it is being filed with a Petition for a Three-Month Extension of Time, making this response due on Monday, November 5, 2007.

Amendments to the Claims:

Reflected in the listing of claims beginning on  
page 2 of this paper.

Remarks/Arguments:

Begin on page 4 of this paper.

## **Amendments to the Claims**

This listing of claims will replace all prior versions and listings of the claims in this application:

### **Listing of the Claims:**

Claims 1-25 (Cancelled).

26. (Previously presented) An assembled bone graft, said assembled bone graft assembled outside the body and suitable for implantation into a human patient, said assembled bone graft comprising: a plurality of machined allograft bone portions layered to form a graft unit, and biocompatible pins traversing said graft unit for holding said graft unit together as an assembled bone graft, said assembled bone graft does not include an adhesive.

27. (Previously presented) An assembled bone graft suitable for implantation in a human patient comprising:

two distinct bone portions of cortical bone, and biocompatible pins, wherein said two distinct bone portions are machined allograft bone portions processed to be suitable for implantation in a human patient, said biocompatible pins are of appropriate diameter and press fitted into machined holes in said two bone portions to hold together said two bone portions to form an assembled bone graft suitable for implantation in humans.

28. (Previously presented) An assembled bone graft suitable for implantation in a human patient comprising two or more distinct, bone portions of machined allograft bone, and pins comprising cortical bone ("cortical bone pins"), said two or more distinct, bone portions having holes therein for receiving said cortical bone pins, said cortical bone pins keeping said two or more distinct, bone portions aligned and connected to form said assembled bone graft free of an adhesive and suitable for implantation in a human.

29. (Previously presented) The assembled bone graft of claim 28 where there are two distinct, bone portions of machined allograft bone.

30. (Previously presented) The assembled bone graft of claim 28, wherein said two or more distinct, bone portions are selected from the group consisting of: cortical bone and cancellous bone.

Claims 31-62 (Cancelled).

## **Remarks**

### **Status of the Claims**

Upon entry of the above amendments, claims 26-30 will remain pending in the present application, claims 31-34, 61 and 62 having been cancelled in the above amendments. Claims 26, 27 and 28 are the independent claims.

### **Summary of the Bases for Objection /Rejection**

Claims 26 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154.

Claims 31-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis).

Claims 31-34 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis).

Claims 31-34 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis).

Claims 26-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates).

Each of these five (5) bases for rejection is addressed in Sections I-V, respectively, which follow.

#### **I. Provisional Rejection Based On Obviousness Type Double Patenting**

Claims 26 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154. The Applicants will address this issue at such time as claims are allowed either in the present application or in the '154 application.

#### **II. 35 U.S.C. § 102(b) over U.S. Pat. 5,147,367 (Ellis)**

Claims 31-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). Applicants maintain that claims 31-34 are

patentable over Ellis. However, claims 31-34 have been cancelled to advance prosecution of the remaining claims. The cancellation of claim 31-34 renders this rejection moot. Therefore this rejection will not be addressed further.

**III. 35 U.S.C. § 103(a) over U.S. Pat. 5,147,367 (Ellis)**

Claims 31-34 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis). Applicants maintain that claims 31-34 are patentable over Ellis. However, claims 31-34 have been cancelled to advance prosecution of the remaining claims. The cancellation of claim 31-34 renders this rejection moot. Therefore this rejection will not be addressed further.

**IV. 35 U.S.C. § 103(a) over U.S. Pat. 5,716,358 (Ochoa) in view of Ellis**

Claims 31-34 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis). Applicants maintain that claims 31-34 are patentable over Ochoa in view of Ellis. However, claims 31-34 have been cancelled to advance prosecution of the remaining claims. The cancellation of claim 31-34 renders this rejection moot. Therefore this rejection will not be addressed further.

**V. 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates)**

Claims 26-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates). Applicants maintain that claims 31-34 and 61-62 are patentable over Siebels in view of Coates. However, claims 31-34 and 61-62 have been cancelled to advance prosecution of the remaining claims. Therefore the rejection with respect to these claims will not be addressed further. With regard to claims 26-30, the Applicants respectfully disagree with the Patent Office's rejection as discussed below.

The Office Action relies on Siebels for its disclosure of "an assembled bone implant made by assembling separate bone implant pieces together by aligning bores of adjacent pieces;" and introducing "pins into the aligned bones to hold the implant pieces

together.” [Office Action at page 5.] However, the only materials actually described in the Siebels reference from which the disks and/or anchoring pins described therein can be made are “fiber reinforced plastic,” see Siebels translation at p. 3, such as “carbon-fiber reinforced plastic.” See Siebels translation at p. 6. The Siebels reference does not describe any other materials from which its implants or anchoring pins can be made.

The Office Action acknowledges that Siebels does not disclose the use of cortical bone for making implant pieces. To make up for this deficiency, the Office Action cites to Coates, alleging that Coates “teaches that it was well known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61.” [Office Action at page 6.] The Office Action then concludes that it would have been obvious to make the discs and pins of Siebels implant out of cortical bone for the same reasons the [sic] Coates teaches doing the same. The Applicants respectfully disagree.

Applicants submit that a person of skill in the art would not combine the teachings of the Siebels and Coates references in the manner required by the Office Action. Such a person would not substitute the fiber reinforced plastic used by Siebels with cortical bone pursuant to Coates. Siebels employs fiber reinforced plastic as the material for its discs. Siebels notes that “Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, **in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.**” See Siebels translation at p. 4 (emphasis added). In contrast, the Coates reference states that there would be concerns about stability when bone is used. For example at column 3, lines 17-32, Coates states “Both allograft and autograft present additional difficulties. Graft alone **may not provide the stability required** to withstand spinal loads.” [Emphasis added.] Coates acknowledges the difficulties in creating implants from allograft or autograft bone. Coates goes on to discuss the difficulty of creating such an implant.

Several attempts have been made to develop a bone graft substitute which avoids the disadvantages of metal implants and bone grafts while capturing advantages of both. In each case, developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been **extremely difficult or impossible.**

[Coates, col. 3, lines 38-39] [emphasis added.] A person of skill in the art would not substitute the fiber reinforced plastic, which is said by Siebels to have rigidity and strength, with cortical bone, which, according to Coates, may not provide the required stability.

Additionally, in discussing the Coates reference, the Office Action also states that “[a]ssembly of the implant pieces was not an issue.” Applicants submit that this is indicative of the nonobviousness. Coates does not even suggest a bone graft assembled from a plurality of allograft bone portions layered to form a graft unit.

For at least these reasons, the combination of the Siebels and Coates references would not have rendered claims 26-30 obvious to a person skilled in the art at the time that the Applicants’ invention was made.

### **Conclusion**

Although the Office Action makes various statements regarding claims 26-34, 61, 62 and the cited references that are now moot in light of the above, applicants expressly reserve the right to challenge such statements in the future should the need arise (for example, if such statement(s) become relevant by appearing in a rejection of any current or future claim).

Claims 26-30 are currently pending. Claims 26-30 currently stand rejected. In view of the amendments and arguments provided herein, Applicants believe that all bases for rejecting claims 26-30 have been overcome. Applicants respectfully submit that claims 26-30 of the instant application are in a condition for allowance. The Examiner is invited to telephone the applicants’ undersigned attorney at (312) 775-8213, if any unresolved matters remain.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Respectfully submitted,

Date: November 5, 2007

By: /Sarah A. Kofflin/  
Sarah A. Kofflin  
Attorney for Applicants  
Registration No. 60,218

McAndrews, Held & Malloy, Ltd.  
500 W. Madison St.  
34<sup>th</sup> Floor  
Chicago, IL. 60661  
Phone: 312-775-8000  
Fax: 312-775-8100

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	09782594			
<b>Filing Date:</b>	12-Feb-2001			
<b>Title of Invention:</b>	Assembled Implant			
<b>First Named Inventor/Applicant Name:</b>	John R. Bianchi			
<b>Filer:</b>	Sarah A. Kofflin/Patricia Walsh			
<b>Attorney Docket Number:</b>	RTI- 112R			
Filed as Large Entity				
<b>Utility      Filing Fees</b>				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				
<b>Extension-of-Time:</b>				
Extension - 3 months with \$0 paid	1253	1	1050	1050

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				1050

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	2426026
<b>Application Number:</b>	09782594
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	9490
<b>Title of Invention:</b>	Assembled implant
<b>First Named Inventor/Applicant Name:</b>	John R. Bianchi
<b>Correspondence Address:</b>	DONALD J. POCHOPIEN McANDREWS, HELD & MALLOY, LTD. CITICORP CENTER, 34TH FLOOR 500 WEST MADISON STREET CHICAGO IL 60661 US 4072280329
<b>Filer:</b>	Sarah A. Kofflin/Patricia Walsh
<b>Filer Authorized By:</b>	Sarah A. Kofflin
<b>Attorney Docket Number:</b>	RTI- 112R
<b>Receipt Date:</b>	05-NOV-2007
<b>Filing Date:</b>	12-FEB-2001
<b>Time Stamp:</b>	17:23:26
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	\$ 1050
RAM confirmation Number	2199

Deposit Account	130017
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

### File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		13980US02_ROA_5-03-07.pdf	138307 <small>cd0a56a0b0d9ce3227731c0de06009030305d5</small>	yes	8
<b>Multipart Description/PDF files in .zip description</b>					
<b>Document Description</b>			<b>Start</b>	<b>End</b>	
Amendment - After Non-Final Rejection			1	1	
Claims			2	3	
Applicant Arguments/Remarks Made in an Amendment			4	8	

### Warnings:

### Information:

2	Fee Worksheet (PTO-06)	fee-info.pdf	8129 <small>19032ae50a10c08aee445025e907d85d2e230231</small>	no	2
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### Warnings:

### Information:

<b>Total Files Size (in bytes):</b>	146436
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

## **EXHIBIT 26**



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1458  
Alexandria, Virginia 22313-1458  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490

52727 7590 01/15/2008  
REGENERATION TECHNOLOGIES, INC.  
c/o MCANDREWS, HELD & MALLOY  
500 WEST MADISON STREET  
34TH FLOOR  
CHICAGO, IL 60661

EXAMINER
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PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
-----------	---------------

01/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Notice of Non-Compliant  
Amendment (37 CFR 1.121)**

Application No.	Applicant(s)	
09/782,594	BIANCHI ET AL.	
Examiner	Art Unit	
Paul B. Prebille	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 05 November 2007 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

**THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:**

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other \_\_\_\_\_.
- ☐ 2. Abstract:
  - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other \_\_\_\_\_.
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has showing amended figures, without markings, in compliance
  - ☐ C. Other \_\_\_\_\_.
- ☒ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending
  - ☒ C. Each claim has not been provided with the proper status of each claim cannot be identified. Note: the status of ever, number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: See Continuation Sheet.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

**TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:**

- Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
- Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

**Extensions of time** are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

**Failure to timely respond** to this notice will result in:

**Abandonment** of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

**Non-entry** of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Paul B. Prebille Primary Examiner  
Legal Instruments Examiner (LIE), if applicable

(571) 272-4758  
Telephone No.



Continuation of 4(e) Other: The amendment filed November 5, 2007 contained claim changes, with respect to the most recent prior amendment, that were not indicated by editorial markings according to 37 CFR 1.121 (c) (2). Therefore, certain status identifiers were not correct. In response to this Notice, the Applicant is required to either (1) correct the status identifier and insert appropriate editorial markings into the claims -or- (2) present the most recent prior claims (i.e. claims 26 to 30) as they appeared in the February 26, 2007 amendment while keeping the status identifiers as "previously presented".

## **EXHIBIT 27**



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490
52727 7590 03/03/2008 REGENERATION TECHNOLOGIES, INC. c/o MCANDREWS, HELD & MALLOY 500 WEST MADISON STREET 34TH FLOOR CHICAGO, IL 60661			EXAMINER PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3774	
			MAE DATE	DELIVERY MODE
			03/03/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

***Notice of Non-Compliant  
Amendment (37 CFR 1.121)***

**Application No.**

09/782,594

**Applicant(s)**

BIANCHI ET AL.

**Examiner**

Paul B. Prebilic

**Art Unit**

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 25 January 2008 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other \_\_\_\_\_.
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other \_\_\_\_\_.
- ☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other \_\_\_\_\_.
- ☒ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: Upon review of the new claim set, the Examiner found that claim 28 has been changed from the February 26, 2007 amendment without editorial marks. In particular, on line 4 of claim 28, the language "cortical bone" has been reinserted without editorial marks even though it was deleted by the February 26, 2007 amendment. Although the Examiner reviewed all the claims filed January 25, 2008, The Applicant is requested to review to review the claims for any other inconsistencies with the prior entered amendment.
  - ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):  
\_\_\_\_\_

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

#### TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

- Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
- Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a Quayle action. If any of above boxes 1, to 4, are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a Quayle action.

Failure to timely respond to this notice will result in:

**Abandonment** of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a Quayle action; or

**Non-entry** of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

/Paul Prebilic/

(571) 272-4758

Legal Instruments Examiner (LIE), if applicable

Telephone No.



## **EXHIBIT 28**

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:  
Bianchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

Group Art Unit: 3738

Examiner: Paul B. Prebilic

) Certificate of Electronic Transmission

) I hereby certify that this correspondence is  
) being transmitted electronically to the U.S.  
) Patent and Trademark Office via EFS on:

) January 25, 2008

) /Sarah A. Kofflin/

) Sarah A. Kofflin

) Registration No. 60,218

) Customer No. 23,446  
)

**Response to Notice of Non-Compliant Amendment**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Non-Compliant Amendment mailed January 15, 2008, Applicants respectfully request entry of the following amendments and a consideration of the response on the merits. This Amendment and Response is believed to be timely because it is being filed before the one month deadline of February 15, 2008.

Amendments to the Claims:

Reflected in the listing of claims beginning on  
page 2 of this paper.

Remarks/Arguments:

Begin on page 4 of this paper.

## **Amendments to the Claims**

This listing of claims will replace all prior versions and listings of the claims in this application:

### **Listing of the Claims:**

Claims 1-25 (Cancelled).

26. (Previously presented) An assembled bone graft, said assembled bone graft assembled outside the body and suitable for implantation into a human patient, said assembled bone graft comprising: a plurality of machined allograft bone portions layered to form a graft unit, and pins comprising cortical bone traversing said graft unit for holding said graft unit together as an assembled bone graft, wherein said assembled bone graft does not include an adhesive.

27. (Previously presented) An assembled bone graft suitable for implantation in a human patient comprising:

two distinct bone portions of cortical bone, and pins comprising cortical bone, wherein said two distinct bone portions are machined allograft bone portions processed to be suitable for implantation in a human patient, said pins are of appropriate diameter and press fitted into machined holes in said two bone portions to hold together said two bone portions to form an assembled bone graft suitable for implantation in humans.

28. (Previously presented) An assembled bone graft suitable for implantation in a human patient comprising two or more distinct bone portions of machined allograft bone, and pins comprising cortical bone, said two or more distinct bone portions having holes therein for receiving said cortical bone pins, said pins keeping said two or more distinct bone portions aligned and connected to form said assembled bone graft free of an adhesive and suitable for implantation in a human.

29. (Previously presented) The assembled bone graft of claim 28 where there are two distinct bone portions of machined allograft bone.

30. (Previously presented) The assembled bone graft of claim 28, wherein said two or more distinct bone portions are selected from the group consisting of: cortical bone and cancellous bone.

Claims 31-62 (Cancelled).

## **Remarks**

### **Status of the Claims**

In response to the Notice of Non-Compliant Amendment Applicant has presented the most recent prior claims as they appeared in the February 26, 2007 amendment while keeping the status identifies as "previously presented." Upon entry of the above amendments, claims 26-30 will remain pending in the present application, claims 31-34, 61 and 62 having been cancelled in the above amendments. Claims 26, 27 and 28 are the independent claims. The Examiner is invited to telephone the applicants' undersigned attorney at (312) 775-8213, if any unresolved matters remain.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Respectfully submitted,

Date: January 25, 2008

By: /Sarah A. Kofflin/  
Sarah A. Kofflin  
Attorney for Applicants  
Registration No. 60,218

McAndrews, Held & Malloy, Ltd.  
500 W. Madison St.  
34<sup>th</sup> Floor  
Chicago, IL 60661  
Phone: 312-775-8000  
Fax: 312-775-8100

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	2769087
<b>Application Number:</b>	09782594
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	9490
<b>Title of Invention:</b>	Assembled implant
<b>First Named Inventor/Applicant Name:</b>	John R. Bianchi
<b>Customer Number:</b>	52727
<b>Filer:</b>	Sarah A. Koffin/Claudette Doss
<b>Filer Authorized By:</b>	Sarah A. Koffin
<b>Attorney Docket Number:</b>	RTI- 112R
<b>Receipt Date:</b>	25-JAN-2008
<b>Filing Date:</b>	12-FEB-2001
<b>Time Stamp:</b>	15:53:31
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
------------------------	----

### File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip (if appl.)	Pages (if appl.)
1	Amendment Copy Claims/Response to Suggested Claims	13980US02_Amendment_1-25-08.pdf	144117 <small>88c9c0bcb0963db17a394d349d7738b A0219d57</small>	no	5

### Warnings:

### Information:

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

## **EXHIBIT 29**

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In the Application of:

Blanchi, John R., *et al.*

Serial No.: 09/782,594

Filed: February 12, 2001

For: "Assembled Implant"

Group Art Unit: 3738

Examiner: Paul B. Prebille

) Certificate of Electronic Transmission

) I hereby certify that this correspondence is  
) being transmitted electronically to the U.S.  
) Patent and Trademark Office via EFS on:

) March 24, 2008

) /Sarah A. Kofflin/

) Sarah A. Kofflin

) Registration No. 60,218

) Customer No. 23,446

Response to Notice of Non-Compliant Amendment

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Non-Compliant Amendment mailed March 3, 2008, Applicants respectfully request entry of the following amendments and a consideration of the response on the merits. This Amendment and Response is believed to be timely because it is being filed before the one month deadline of April 3, 2008.

Amendments to the Claims:

Reflected in the listing of claims beginning on  
page 2 of this paper.

Remarks/Arguments:

Begin on page 4 of this paper.

## **Amendments to the Claims**

This listing of claims will replace all prior versions and listings of the claims in this application:

### **Listing of the Claims:**

Claims 1-25 (Cancelled).

26. (Previously presented) An assembled bone graft, said assembled bone graft assembled outside the body and suitable for implantation into a human patient, said assembled bone graft comprising: a plurality of machined allograft bone portions layered to form a graft unit, and pins comprising cortical bone traversing said graft unit for holding said graft unit together as an assembled bone graft, wherein said assembled bone graft does not include an adhesive.

27. (Previously presented) An assembled bone graft suitable for implantation in a human patient comprising:

two distinct bone portions of cortical bone, and pins comprising cortical bone, wherein said two distinct bone portions are machined allograft bone portions processed to be suitable for implantation in a human patient, said pins are of appropriate diameter and press fitted into machined holes in said two bone portions to hold together said two bone portions to form an assembled bone graft suitable for implantation in humans.

28. (Previously presented) An assembled bone graft suitable for implantation in a human patient comprising two or more distinct bone portions of machined allograft bone and pins comprising cortical bone, said two or more distinct bone portions having holes therein for receiving said pins, said pins keeping said two or more distinct bone portions aligned and connected to form said assembled bone graft free of an adhesive and suitable for implantation in a human.

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29. (Previously presented) The assembled bone graft of claim 28 where there are two distinct bone portions of machined allograft bone.

30. (Previously presented) The assembled bone graft of claim 28, wherein said two or more distinct bone portions are selected from the group consisting of: cortical bone and cancellous bone.

Claims 31-62 (Cancelled).

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## **Remarks**

### **Status of the Claims**

In response to the Notice of Non-Compliant Amendment Applicant has presented the most recent prior claims as they appeared in the February 26, 2007 amendment while keeping the status identifiers as "previously presented." Upon entry of the above amendments, claims 26-30 will remain pending in the present application, claims 31-34, 61 and 62 having been cancelled in the above amendments. Claims 26, 27 and 28 are the independent claims. The Examiner is invited to telephone the applicants' undersigned attorney at (312) 775-8213, if any unresolved matters remain.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Respectfully submitted,

Date: March 24, 2008

By: /Sarah A. Kofflin/  
Sarah A. Kofflin  
Attorney for Applicants  
Registration No. 60,218

McAndrews, Held & Malloy, Ltd.  
500 W. Madison St.  
34<sup>th</sup> Floor  
Chicago, IL 60661  
Phone: 312-775-8000  
Fax: 312-775-8100

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	3041812
<b>Application Number:</b>	09782594
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	9490
<b>Title of Invention:</b>	Assembled Implant
<b>First Named Inventor/Applicant Name:</b>	John R. Bianchi
<b>Customer Number:</b>	52727
<b>Filer:</b>	Sarah A. Kofflin/Claudette Doss
<b>Filer Authorized By:</b>	Sarah A. Kofflin
<b>Attorney Docket Number:</b>	RTI- 112R
<b>Receipt Date:</b>	24-MAR-2008
<b>Filing Date:</b>	12-FEB-2001
<b>Time Stamp:</b>	15:29:07
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
------------------------	----

### File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		13980US02_Amendment_3-24-08.pdf	144919	yes	5
			2b352a525478ed79d122c2e1e7801fa1c2429b3		

Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Amendment Copy Claims/Response to Suggested Claims	1	1	
Amendment Copy Claims/Response to Suggested Claims	2	3	
Amendment Copy Claims/Response to Suggested Claims	4	5	

**Warnings:**

**Information:**

<b>Total Files Size (in bytes):</b>	144919
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**  
 If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**  
 If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**  
 If a new international application is being filed and the International application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

## **EXHIBIT 30**



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1455  
Alexandria, Virginia 22311-1455  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490
53727 7590 04/04/2008 REGENERATION TECHNOLOGIES, INC. c/o MCANDREWS, HELD & MALLOY 500 WEST MADISON STREET 34TH FLOOR CHICAGO, IL 60661			EXAMINER PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			5774	
			MAIL DATE	DELIVERY MODE
			04/04/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/782,594	<b>Applicant(s)</b> BIANCHI ET AL	
	<b>Examiner</b> Paul B. Prebille	<b>Art Unit</b> 3774	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 26-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date _____<br>5) <input type="checkbox"/> Notice of Informal Patent Application<br>6) <input type="checkbox"/> Other: _____ |
|---|---|

***Double Patenting***

Upon review of copending application 09/941,154, it was noted that claim 79 was cancelled in the most recent amendment dated November 19, 2007. For this reason, the double patenting rejection was withdrawn. However, a review of related applications to the present application reveals that applications 09/905,683, 10/387,322, and 09/941,154 present potential double patenting issues in that the claimed subject matter therein is quite similar to the presently claimed subject matter. The Applicant is respectfully requested to apprise the Examiner of any double patenting conflicts among this application, the applications mentioned *supra*, and any other applications or patents that they are aware.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation. Siebels also

discloses that "the hollow space is filled with bone material or bone cement for the purpose of a radial anchoring of the ring"; see page 5 of the translation. Also, on page 11 of the translation, Siebels discloses that "extraneous bone material, or the patient's own bone material" can be used to fill the cavity. However, Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6).

Coates, however, teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner's position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

Regarding claims 28-30, the spacers of Coates can have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Any segment thereof could be said to be made of cortical bone. "Allograft" is a homograft (i.e. from the same species) that is allogenic (i.e. genetically distinct) to the recipient; see Merriam-Webster OnLine at [www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft](http://www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft). Since the bone of Coates is capable of being used as a bone graft unit upon the death of the individual, it is considered an allograft bone portion with respect to another human being to the

extent that this language can be given patentable weight. The site or source of the material is relative to how it can be used and is not indicative of the material itself because the bone implants of Coates are allogenic with respect to another human being. For these reasons, the separated bone pieces are grafts and allografts when these terms are given their broadest reasonable interpretation. The claim language requiring "machined" bone portions is not structurally distinguishing from that disclosed by Coates because it does require any particular structure in the device; see MPEP 2113 that is incorporated herein by reference.

#### ***Response to Arguments***

The Applicant's arguments filed November 5, 2007 have been fully considered but they are not persuasive in all cases.

The Applicant argues that Siebels only means making implants out of plastic even when it states "solid disks can be manufactured of any biologically compatible material." This argument is not considered persuasive because the plain language of Siebels does not suggest such a limited understanding and because the use of plastics is considered to be mere exemplification or preference for making the device. Moreover, Coates provides the motivation to make the implant pieces of Siebels out of bone.

Next, the Applicant argues that the prior art references teach away from the combination suggested by the Examiner because Siebels requires an "extraordinarily easy" way of making the implants thereof. However, the Examiner asserts that Siebels is referring more to the assembly and sizing of the device just prior to surgery rather

than the overall process of making. Furthermore, if the prior art had difficulty in making bone grafts from the perspective of Coates, than Coates at least implicitly can be said to overcome such difficulties. For this reason, there would be nothing stopping an ordinary artisan from applying the teaching of Coates to that of Siebels to arrive at the claimed invention. Moreover, a preference for a certain material, as in Siebels, is not a teaching away from other materials; see MPEP 2123 (II) that is incorporated herein by reference thereto.

Moreover, the Examiner asserts that Siebels desires easily assembleable disks that enable the surgeon to quickly assemble pre-manufactured disks into an appropriately sized implant. Coates, on the other hand, states that implants made with bone have had problems due primarily to their shapes and cancellous bone make-up. Coates discloses one example of a bone dowel that was not stable due to shape and cancellous bone make-up see the discussion of Cloward on column 3. Assembly of the implant pieces was not an issue. Coates solved the problems of the prior art by making the implant primarily of cortical bone and making the implant into a rectangular shape with vertebra engaging teeth and ridges to prevent migration. Consequently, the Examiner asserts that Coates is discussing an entirely different issue than that of Siebels. For these reasons, the Applicant's line of reasoning is not considered persuasive.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/  
Paul Prebilic  
Primary Examiner  
Art Unit 3774

# **Notice of References Cited**

Application/Control No.

09/762,594

Applicant(s)/Patent Under  
Reexamination  
BIANCHI ET AL

Examiner

Paul B. Prebilic

Art Unit

3774

Page 1 of 1

## **U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-7,300,465	11-2007	Paul et al.	623/17.11
*	B	US-7,347,873	03-2008	Paul et al.	623/17.11
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

## **FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

## **NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

## **EXHIBIT 31**

<b>NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES</b>		Docket Number (Optional) 13980US02						
<b>Electronic Filing Date:</b> July 1, 2008  Signature <u>/Sarah A. Kofflin/</u> Typed or printed name <u>Sarah A. Kofflin</u>	In re Application of John R. Bianchi  <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; padding: 2px;">Application Number 09/762,594</td> <td style="width: 40%; padding: 2px;">Filed February 12, 2001</td> </tr> <tr> <td colspan="2" style="padding: 2px;">For Assembled Implant</td> </tr> <tr> <td style="padding: 2px;">Art Unit 3774</td> <td style="padding: 2px;">Examiner Paul B. Prebilo</td> </tr> </table>		Application Number 09/762,594	Filed February 12, 2001	For Assembled Implant		Art Unit 3774	Examiner Paul B. Prebilo
Application Number 09/762,594	Filed February 12, 2001							
For Assembled Implant								
Art Unit 3774	Examiner Paul B. Prebilo							
Applicant hereby appeals to the Board of Patent Appeals and Interferences from the decision of the examiner.  The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) <span style="float: right;">\$ <u>500</u></span>  <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: <span style="float: right;">\$ _____</span>  <input type="checkbox"/> A check in the amount of the fee is enclosed.  <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.  <input checked="" type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.  <input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. <u>13-0017</u>. I have enclosed a duplicate copy of this sheet.  <input type="checkbox"/> A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.                 </div> </div> <p><b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>I am the _____</p> <input type="checkbox"/> applicant/inventor.  <input type="checkbox"/> assignee of record of the entire interest.                      See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.                      (Form PTO/SB/06)  <input checked="" type="checkbox"/> attorney or agent of record.                      Registration number <u>69,216</u>.  <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34.                      Registration number if acting under 37 CFR 1.34. _____                 </div> <div style="width: 35%; text-align: right;"> <p><u>/Sarah A. Kofflin/</u>                      _____                      Signature  <u>Sarah A. Kofflin</u>                      _____                      Typed or printed name  <u>312-775-8000</u>                      _____                      Telephone number  <u>July 1, 2008</u>                      _____                      Date</p> </div> </div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.</p>								
<input type="checkbox"/> *Total of _____ forms are submitted.								

This collection of information is required by 37 CFR 41.31. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22315-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22315-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	09782594			
<b>Filing Date:</b>	12-Feb-2001			
<b>Title of Invention:</b>	Assembled implant			
<b>First Named Inventor/Applicant Name:</b>	John R. Bianchi			
<b>Filer:</b>	Sarah A. Kofflin/Stephanie Holmes			
<b>Attorney Docket Number:</b>	RTI- 112R			
Filed as Large Entity				
<b>Utility      Filing Fees</b>				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
Notice of appeal	1401	1	510	510
<b>Post-Allowance-and-Post-Issuance:</b>				
<b>Extension-of-Time:</b>				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				510

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	3548858
<b>Application Number:</b>	09782594
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	9490
<b>Title of Invention:</b>	Assembled Implant
<b>First Named Inventor/Applicant Name:</b>	John R. Bianchi
<b>Customer Number:</b>	52727
<b>Filer:</b>	Sarah A. Kofflin/Stephanie Holmes
<b>Filer Authorized By:</b>	Sarah A. Kofflin
<b>Attorney Docket Number:</b>	RTI- 112R
<b>Receipt Date:</b>	01-JUL-2008
<b>Filing Date:</b>	12-FEB-2001
<b>Time Stamp:</b>	13:17:02
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$510
RAM confirmation Number	9212
Deposit Account	130017
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Notice of Appeal Filed	13980US02-Notice_of_Appeal_07-01-08.pdf	87888 +932f8622905c5d8348768b731857hec330a50273c	no	1

**Warnings:****Information:**

2	Fee Worksheet (PTO-06)	fee-Info.pdf	8120 21c5d84e05e01a2f3c828e0830521d278d77038	no	2
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**Warnings:****Information:****Total Files Size (in bytes):**

96008

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

## **EXHIBIT 32**

Attachment A

0517030EP

PTO 2005-1131

Translated from the GERMAN

European Patent Office

EUROPEAN PATENT APPLICATION

O 517 030 A2

IPC: A61F 2/44

Application number: 92108405.9

Date of application: May 19, 2005

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Priority: June 4, 1991 DE 4118316

May 8, 1992 DE 4215137

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Applicant: MAN Ceramics GmbH

Inventor: Wolfgang Siebels, Spitzwegstraße 17, D-8360 Deggendorf and Rudolf Ascherl, Türkenstraße 53, D-8000 Munich

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[Title in German of the object of the invention:]  
Wirbelkörperimplantat

INTRAVERTEBRAL BODY IMPLANT

The invention pertains to an intravertebral (intraspinal) body implant for vertebral (spinal) columns consisting of at least a rigid element.

Intravertebral bodies have different size along a spinal column, and vary from patient to patient. Therefore, when an

intravertebral body is substituted by an implant, it is necessary that the implant is matched to the effective size of the interval between the adjacent intravertebral bodies.

In order for an allowance to be made for this interval, implants were developed (DE 30 23 942 C3), which essentially consist of two parts, which are connected to one another by means of a threaded connection, and whose axial height can be changed by rotation, or which can be matched to the interval between the intravertebral bodies. By means of transverse bolts or other means of anchoring, the two parts are anchored in a way, which is resistant to torsional stress or prevents a rotation. Therewith, by means of a single embodiment an entire range of intervals can indeed be covered, however the adjustment in height takes relatively much time in the case of a fine thread.

An implant of the generic kind, which rectifies this imperfection, is known from the WO 90/00037, which implant is inserted solely between two vertebrae by means of a tool. However, the approximately rectangular implant is assembled out of intricate individual parts.

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is

achieved with the help of the features, cited in claim 1.

Not only is a disk easily inserted into a spinal gap but it can also be manufactured in such a way that it can very easily and dimensionally correct be matched to a certain case of application. For example, in the case of a specific application, it is thus possible that first of all the disk is cut out of a prefabricated solid or hollow strand, sterilized, or separated in sterile state with the help of a sterile grinding tool and sterile water. By using a coarse-grained grinding, respectively cutting tool, a rough surface, promoting the growth process, is imparted to the sectional areas of the implant (spinal) disk, which form the support for the intravertebral bodies.

Basically, the use of a disk of any configuration, be it of round, polygonal, irregular contour, is possible. Also, the inner contour of an annular disk can be created as occasion demands.

The contact surface of a disk, which is being used for the adjacent intravertebral bodies, is designed as structured for the promotion of the growth process, and is selected as being coarse, or running in different directions. Anchoring means in the form of projecting tips or spikes are used for the immediate securing of the prosthesis after the implantation takes place.

The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists

of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.

In accordance with yet another embodiment of the invention, two or more disks are assembled, in order for an intravertebral body implant to be produced. In that case, a stock of an assortment of disks, having different height and diameter, is kept, available at hand. For the purposes of an implantation, the interval between the vertebrae is measured, and correspondingly thick, respectively high, disk of the assortment are combined together in such a way, that they have the desired vertical dimension in their entirety. The selected disks - they consist of parts of analogous shape, only having different height - are stacked one above another, in accordance with the modular principle, and are inserted as ready-made implant between the intravertebral bodies, which - to this end - are slightly pulled apart. Also, in this case, after the insertion of the implant, a regulation or adjustment of the latter inside the patient body is not required.

With the help of a computer, the disks' heights, which are to be combined, are instantaneously determined so that a minimal time input is required between the spinal interval measurement and the reception of the insertable implant. The radial anchoring, and the anchoring, preventing a rotation and resisting the torsional stress, of the assembled disks, can be mastered in a multifarious way.

In accordance with an embodiment of the invention, the disks have aligned boreholes, into which anchoring pins or studs can be inserted. In that embodiment, the disks are radially connected to one another, and also in such a way that they resist the torsional stress [i.e. possess torsional strength], and cannot rotate. Moreover, from a manufacturing engineering standpoint, the manufacturing of the disks is very easy.

Another possibility consists in that the disks are directly produced as having molded anchoring means, such as, e.g., groove and tongue, pin [stud] and boreholes.

Also, the disk packages can be designed as annular disks whereby the hollow space is filled with bone material or bone cement for the purposes of a radial anchoring of the rings. It is advantageous when the inner jacket of the annular disks is irregular, or has geometrical irregularities. Each deviation from the circular cylindrical shape is used for a torsionally resistant anchoring of the stacked disks when the hollow space of the annular disks is filled up with a hardening material. In

order for a reliable support of the implant - which is designed as a disk stack - to be achieved between adjacent intravertebral bodies, end-disks are provided, having a rough frontal side. The roughness can be generated by means of a structured area, projecting tips, undulations, and similar.

In each embodiment, it is possible to glue the disks with one another into a solid unit, e.g., with the help of PMMA\* cement, if required, or if functionally feasible. [\*Translator's note: PMMA = polymethyl methacrylate].

Preferably, the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means - according to the design of the implant - can consist of the same, or another material. The manufacturing of the entire implant of CFP has the advantage that the implant does not bring about any scattering of rays, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of all image-producing methods (CT\*, MR\*) [\*Translator's note: CT = charge-transfer (absorption band or electron-transfer band); MR = magnetic resonance).

Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ["washers"] can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled

through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.

Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages [packings] can be designed.

The invention is elucidated in greater detail by means of exemplified embodiments, diagrammatically represented in the drawing, wherein

Figs. 1 and 2 show a first exemplified embodiment,

Figs. 3 and 4 show a second exemplified embodiment

Figs 5 thru 8 show another exemplified embodiment, each.

The notion that the surgeon directly assembles the spinal body substitute (replacement set) on the very spot by knowing the actual overall dimensions and without the help of a prosthesis

technician, forms the basis of the invention. To this end, a stock of strands, having different diameter and/or a supply of an assortment of spare implant components, having different diameter and height, is maintained so that for each relevant case either a corresponding thick disk needs to be separated from the relevant strand, or the relevant number of components, having relevant dimensions ought to be taken out, and assembled without threaded [screw] adjustments or other types of handling. In the last case, the selection of the disks according to their height can take place by means of a computer.

The base of an assembled implant consists in the stacking of prefabricated disks whereby these disks can have a round, polygonal or irregular outer contour. Solid disks or also annular disks can be used in their capacity as components. Disk assortment sets, having different diameters, are necessary whereby each assortment of a diameter is outfitted with disks, having different diameter. If one is absolutely certain about the diameter of the disk to be used, the corresponding heights are yet to be selected within the framework of the corresponding disk batch [assortment set] so that after the selected disks are assembled, the required implant height is thus produced.

For example, in order for the assortment with respect to the disk height to be maintained as small as possible, few high dimensions can be provided, which are correspondingly supplemented with lower disks, e.g., having a thickness of

several millimeters.

Fig. 1 shows an exemplified embodiment, in which a ready-made implant 10 is assembled out of three thicker disks 11, a thin disk 12, and two end-disks 13 and 14.

As diagrammatically represented in Fig. 2, the disks, 11 thru 14, consist of round annular disks, having an inner borehole 15, and four boreholes 16, respectively, which are equitably distributed over the annular disk. Anchoring pins (studs) 17 are introduced into these boreholes 16. In accordance with the embodiment, depicted in Fig. 1, the pins 17 are connected with one of their respective ends 18 to a disk 11, 13 while they protrude with the other end 19 into the borehole of the subsequent disk 11. In this embodiment, an end-disk 14 is designed without pin (stud). In an analogous way, the thin disks 12 have solely boreholes 16.

Self-evidently, it is also possible to produce the pins as structural components separated from the disks 11 thru 14 so that the pins are introduced into the boreholes 16 only when the assembly of an implant 10 takes place.

Instead of pins, groove-and-tongue systems can also be provided as anchoring means in each possible configuration.

Fig. 3 shows an exemplified embodiment, in which the disks 21 are provided with an annular (ring) spring 22 on one of the frontal sides whereas, on the other frontal side, they are provided with an annular groove 23, aligned with the annular

spring 22. In order for an anchoring to be also achieved in the torsional direction, spring segments 24 can be provided instead of the annular [ring] springs 22, as indicated by the dotted line in Fig. 4, which spring segments engage into corresponding grooved segments of the next disk.

In the diagrammatically represented exemplified embodiments, there were shown round disks, having a circularly symmetric distribution of the anchoring elements. It is self-evident that any asymmetric arrangement of the anchoring elements as well as of any outer contour of the disks is possible as long as the latter are in agreement with the contour of the intravertebral bodies.

From the standpoint of manufacturing engineering, annular disks or solid disks can easily be manufactured of any biologically compatible material because they are not bound to a particular shaping. The shape can even partially be matched to the manufacturing method. Manufacturing methods, which are adequate for the series-manufacturing are winding or pulling of bonded-fiber tubes, out of which the disks are sawn off, cut off, or separated, either as individual element or as elements for the disk packings [packages], described above. In the winding method, fibers or fibrous mats are used in accordance with known methods. In the braiding method, as depicted in Fig. 5, a correspondingly shaped bar-shaped mandrel 30, e.g., having a rectangular cross-section, is passed through a thread eyelet [guide] 31, and, in

doing so, it is surrounded with bundles of longitudinally directed, unidirectional (UD) fibers 32, impregnated with matrix, as well as with outer braiding fibers 32. After the solidification of the matrix, annular disks 35 are separated out of the bonded-fiber tube thus produced, whereby the mandrel is removed prior to or after the separation of the annular disks. The strand, which is designed as bonded-fiber tube, is used for the manufacturing of individual disks as well as for the manufacturing of a disk package, as depicted in Fig. 1.

When needed, individual disks 35 are separated as wedge-shaped ones (Fig. 6,  $(h_1 > h_2)$ ). In the neutral area 37, there can be provided openings 38, which are used to engage the implantation tools and fixation means, such as staples [cramp irons; clams; or clips] 39.

The hollow space 36 can be filled up with extraneous bone material, or with patient's own bone material, or with bone cement, which can also be introduced through the opening 38. When the disks are assembled, the bone cement is also used for the anchoring of the disks in the radial direction, and - due to the non-circular symmetric inner cross-section 36 - in the torsional direction as well. Instead of the rectangular inner cross-section, any other configuration - save the circular shape - can be selected, in order for a free rotational motion between the disks to be precluded.

Fig. 7 shows a shape, having a cylindrical inner jacket 40, which is outfitted with an elevation 42 for torsional anchoring.

If need arises, the disks or annular disks are provided with a starter foil 43- as shown in Fig 7 - surrounding adhesive cartridges 44. When two disks 45 for the formation of the implant are placed one above another, and axially compressed, the adhesive cartridges 44 burst open, so that the adhesive is distributed between the disks 45, and connects the disks with one another. The adhesive connection can be used as single connection or supplementarily to the aforementioned anchoring means.

In the embodiment in accordance with Fig. 7, there are shown additional boreholes 46, which are radially guided through the annular disk 45. They are used for the introduction of the bone cement or bone material into the hollow space 47.

On their free frontal end, used as the support for the spinal bones, the end-disks 13, 14 of an implant 10 have a surface 20, which is rough, structured, or provided with discrete elevations. In interaction with the adjacent intravertebral bodies 50, 51, which are pressing against the implant 10, the said elevations should guarantee the anchoring inside the spinal column, and be used as growth help. As described above, bone cement or material 53 can be pressed - if need arises - through a non-diagrammatically represented radial borehole into the inner borehole 15 up to the adjacent intravertebral body 50, 51. In the case of a single-disk implant, both sides are correspondingly

designed. A rough surface can be directly formed within the framework of the separation process from strand by using a coarse-grained cutting tool.

The implantation of an intervertebral disk substitute and/or an intravertebral fibrocartilage [intravertebral ligament; intervertebral cartilage] of this kind is not subject to any system-specific problems. If the surgical step has gone so far that the interval between the adjacent vertebral bodies can be adjusted, the assembly of the disk-heights for the implant is calculated in the computer with the help of this value, selected, and assembled, or with the help of a precisely adjustable tool, the disk is separated from the strand. The adjacent vertebral bodies are somewhat pulled apart, and the implant, respectively the disk, assembled within the framework of the modular method, is inserted. As far as the implant is concerned, no additional manipulation procedures or handling are necessary save for the placement of the implant. Besides the implant height, the diameter of the implant also varies. Hence, the disk and/or strand assortment is also to be supplied according to cross-sectional areas.

Finally, in Fig. 8, there is shown a hollow strand 50, having an irregular configuration, which hollow strand is formed out of 1 to 20 braidings 51. A mandrel, which is not diagrammatically represented, is often pulled through the annular thread eyelet of a braiding machine, and, in doing so, lined with

many braidings and matrix material, respectively. With the help of separating disks, the disks 53 for an implant or implant element, are cut out at separating lines 52.

#### Patent Claims

1. Implant for spinal columns, consisting of at least a rigid element, characterized in that the implant consists of at least a disk (11 thru 14, 21, 35, 45, 53), which can be directly inserted between two adjacent vertebral [intravertebral] bodies, and according to the spinal position has parallel contact surfaces [support surfaces] or contact surfaces, which are at an angle with respect to one another.
2. Implant as claimed in claim 1, characterized in that the disk is designed as annular disk (35, 45, 53), having regular or irregular circumference, and that the inner circumference of the disk has a polygonal or irregular cross-section.
3. Implant as claimed in claim 1 or 2, characterized in that the contact surfaces of the disks (14, 25, 53) have roughness, pore undulations, or other unevennesses.
4. Implant as claimed in claim 1, characterized in that the contact surfaces of the disks (14, 35, 53) have protruding tips or spikes (20).
5. Implant as claimed in one of the preceding claims, characterized in that the disk (45) has channels (46) into which bone cement or bone material can be introduced.

6. Implant as claimed in one of the preceding claims, characterized in that the disks (11 thru 14, 21, 35, 45, 53) consist of fiber-reinforced plastic, and are made within the framework of the winding method or of wound up (batched up) fiber mats (fiber webs).

7. Implant as claimed in one of the preceding claims, characterized in that the disk (53) is cut out of a strand (32, 33, resp. 50).

8. Implant as claimed in claim 7, characterized in that the strand (hank; rope) (32, 33 or 50) consists of unidirectional fibers (32 and/or braiding layers (31, 51).

Translated by John M Koytcheff, M.Sc. (Engrg.);  
Postgraduate WHO Fellow (Env. Engrg.); USNWC Alumnus

The USPTO Translator (GERMAN & Germanic languages)  
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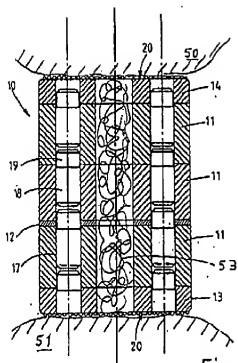


Fig. 1

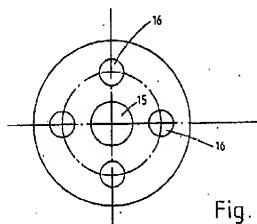


Fig. 2

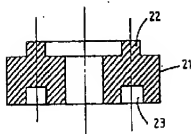


Fig.3

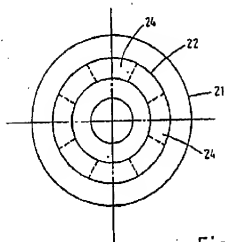


Fig.4

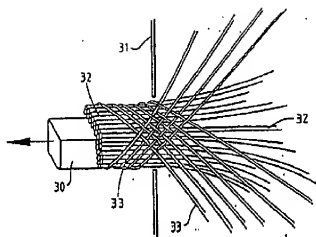


Fig. 5

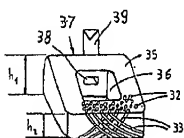


Fig. 6

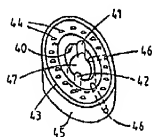


Fig. 7

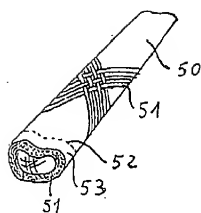


Fig. 8



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# EUROPÄISCHE PATENTANMELDUNG

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⑥ Anmelder: MAN Ceramics GmbH  
Wertstrasse 17, Postfach 13 60  
W-8360 Deggendorf(DE)

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⑧ Erfinder: Siebels, Wolfgang  
Spitzwegstrasse 4  
W-8360 Deggendorf(DE)  
Erfinder: Ascherl, Rudolf, Dr.  
Türkenstrasse 52  
W-8000 München 40(DE)

⑨ Benannte Vertragsstaaten:  
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⑩ Wirbelkörperimplantat

⑪ Als Implantat für Wirbelsäulen wird eine Scheibe (11) vorgeschlagen, die alleine oder zu mehreren gestapelt (11 bis 14) zwischen Wirbelkörper einsetzbar sind. Einzelne Scheiben werden nach Bedarf von einem Strang abgeschnitten, wobei die Scheibendicke dem Einzelfall genau angepaßt werden kann. Diese Implantate eignen sich insbesondere für Halswirbel sowie als Ersatz nach der Entfernung von Bandscheiben. Für die Bildung eines Implantats aus mehreren übereinandergestapelten Scheiben kann ein entsprechendes Sortiment von Scheiben bereitgestellt werden, die sich sowohl im Durchmesser als auch in der Höhe unterscheiden. Für den jeweiligen Anwendungszweck werden demzufolge Scheiben mit entsprechender Dicke ausgesucht und zusammengesetzt, so daß sie insgesamt die erforderliche Höhe des Implantats ergeben. Verschraubungen und insbesondere längere Handhaben im eingesetzten Zustand des Implantats sind bei dem erfindungsgemäßen Implantat nicht erforderlich.

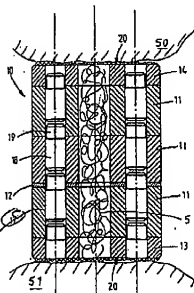


Fig. 1

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Auch die Scheibenpackungen können als Ringscheiben ausgebildet werden, wobei der Hohlraum zur radialen Verankerung der Ringe mit Knochenmaterial oder -zement ausgefüllt werden kann. Vorteilhaft ist es, wenn der Innenmantel der Ringscheiben unregelmäßig ist oder geometrische Unregelmäßigkeiten aufweist, jede Abweichung von der kreiszylindrischen Form dient zur drehsicheren Verankerung der aufgestapelten Scheiben, wenn der Hohlraum der Ringscheiben mit einem härtenden Material ausgefüllt wird.

Für den sicheren Halt des als Scheibenstapel ausgebildeten Implantats zwischen den angrenzenden Wirbelkörpern werden Endscheiben mit einer rauen Stirnseite vorgesehen. Die Rauigkeit kann durch eine strukturierte Oberfläche, herausragende Spitzen, Wellen und dergleichen erzeugt werden.

In jeder Ausführung ist es möglich, die Scheiben zu einer soliden Einheit miteinander zu verkleben, z.B. mit PMMA-Zement, wenn erforderlich oder zweckmäßig.

Die Scheiben werden vorzugsweise aus einem kohlenstoffstärkten Kunststoff (CFK) hergestellt, wobei die Verankerungsmittel je nach Ausgestaltung des Implantats aus demselben oder einem anderen Material bestehen können. Die Herstellung des gesamten Implantats aus CFK hat den Vorteil, daß das Implantat keine Streuung von Strahlen bewirkt, so daß die Wirbelsäule und das angrenzende biologische Gewebe auch nach dem Implantieren eines Wirbelkörperersatzes mit allen bildgebenden Verfahren (CT, MR) untersucht werden kann.

Bekannte Wickeltechniken lassen sich zur serienmäßigen Fertigung der Implantat-Elemente anwenden. Die Ringscheiben können beispielsweise mittels einer Flechtmaschine, die zusätzlich mit unidirektionalen Fasern (UD) bestückt ist, hergestellt werden. Mittels eines Stabdornes, der durch das Fluchtauge gezogen und mit UD-Fasern und Flachweil umlagert wird, wird ein Faserverbundrohr in einem Arbeitszug hergestellt, von dem dann die Ringscheiben abgeschnitten werden. Der Stabdorn, dem ist vorzugsweise aus dem auch als Trennmittel verwendbaren PTFE (Polytetrafluorethylen). Der Stabdorn kann dabei ein Vlecke als Querschnitt haben oder über die Länge Nuten und/oder Erhebungen aufweisen, wodurch im Faserverbundrohr bzw. in den Ringscheiben die für die drehsichere Verankerung erforderliche Innentallgeometrie direkt bei deren Herstellung gebildet wird.

Auch Wickelverfahren unter Anwendung von Fasern oder Faserlegungen erlauben fertigungstechnisch einfache und für Serienfertigung geeignete Herstellverfahren. Es können einheitliche Streifen die Einzelscheiben und die Scheibenpackungen konzipiert werden.

Die Erfindung wird anhand von in der Zeich-

nung schematisch dargestellten Ausführungsbeispielen näher erläutert. Es zeigen:

Figuren 1 und 2

ein erstes Ausführungsbeispiel,

Figuren 3 und 4

ein zweites Ausführungsbeispiel,

Figuren 5 bis 8

je ein weiteres Ausführungsbeispiel.

Der Erfindung liegt der Gedanke zugrunde, daß der Chirurg an Ort und Stelle direkt nach Kenntnis der tatsächlichen Abmessungen den Wirbelkörperersatz zusammenstellt, ohne die Hilfe eines Prothesentechnikers. Dazu wird ein Vorrat von Stücken unterschiedlicher Durchmesser und/oder eines Sortimentes von Implantatkomponenten unterschiedlicher Durchmesser und Höhen gehalten, so daß für den jeweiligen Fall entweder eine entsprechende dicke Scheibe aus dem entsprechenden Stang herausgetrennt oder die entsprechende Anzahl von Komponenten mit entsprechenden Abmessungen herausgeholt und zusammengesetzt zu werden braucht, ohne Schraubstapler oder andere Handgriffe vornehmen zu müssen. Die Auswahl der Scheiben nach ihrer Höhe im letzten Fall kann mittels eines Rechners erfolgen.

Die Grundlage eines zusammengesetzten Implantats besteht im Aufstapeln von vorgefertigten Scheiben, wobei diese Scheiben eine runde, mehrrecksige oder unregelmäßige Außenkontur haben können. Es können volle Scheiben oder auch Ringscheiben als Komponenten verwendet werden. Es werden Scheibenätze mit unterschiedlichen Durchmessern benötigt, wobei jeder Satz eines Durchmessers mit Scheiben unterschiedlicher Höhe bestückt ist. Steht der Durchmesser des einzusetzenden Implantats fest, so werden in dem entsprechenden Scheibenatz noch die entsprechenden Höhen ausgesucht, so daß nach dem Zusammensetzen der gewählten Scheiben sich die erforderliche Implantathöhe ergibt.

Um das Sortiment bezüglich der Scheibenhöhe möglichst klein zu halten, können beispielsweise wenige hohe Abmessungen vorgesehen werden, die mit niedrigen Scheiben, z.B. millimetrischen Scheiben, entsprechend ergänzt werden.

In Fig. 1 ist ein Ausführungsbeispiel gezeigt, bei dem ein fertiges Implantat 10 aus drei dickeren Scheiben 11, einer dünnen Scheibe 12 und zwei Endscheiben 13 bzw. 14 zusammengesetzt ist.

Wie in Fig. 2 dargestellt ist, bestehen die Scheiben 11 bis 14 aus runden Ringscheiben mit einer Innenbohrung 15 und jeweils vier regelmäßig auf die Ringscheibe verteilten Bohrungen 16. In diese Bohrungen 16 werden Verankerungsstifte 17 eingeführt. Gemäß der Ausführung nach Fig. 1 sind die Stifte 17 mit ihren jeweils einem Ende 18 mit einer Scheibe 11, 13 verbunden, während sie mit dem anderen Ende 19 in die Bohrung einer näch-

pern feststellbar ist, wird mittels dieses Wertes im Rechner die Zusammensetzung der Scheibenenden für das Implantat errechnet, herausgesucht und zusammengesetzt oder mittels eines genau einstellbaren Werkzeugs die Scheibe vom Strang abgetrennt. Die angrenzenden Wirbelkörper werden etwas auseinandergezogen und das im Baukastensystem zusammengesetzte Implantat bzw. die Scheibe zwischengelegt. Außer dem Platzieren des Implantats sind keine weiteren Handgriffe bezüglich des Implantats notwendig. Außer der Implantathöhe variiert auch der Durchmesser des Implantats. Das Scheiben- und/oder Strangsoriment ist daher auch nach Querschnitten zu bestücken.

In Fig. 8 ist schließlich ein hohler Strang 50 unregelmäßiger Konfiguration gezeigt, der aus 1 bis 20 Flechtwerken 51 gebildet ist. Ein nicht gezeigter Dorn wird entsprechend oft durch das Ringladenaugen einer Flechtmaschine gezogen und dabei mit entsprechend vielen Flechtwerken und Matrixmaterial überzogen. Mit Trennscheiben werden an Trennlinien 52 die Scheiben 53 für ein Implantat oder Implantatelement herausgeschnitten.

#### Patentansprüche

1. Implantat für die Wirbelsäule, bestehend aus mindestens einem steilen Element, dadurch gekennzeichnet, daß das Implantat aus mindestens einer Scheibe (11 bis 14, 21, 35, 45, 53) besteht, die direkt zwischen zwei angrenzenden Wirbelkörpern zwischenlegbar ist und je nach Wirbelhöhe parallel oder zueinander im Winkel stehende Auflageflächen hat.
2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Scheibe als Ringscheibe (35, 45, 53) mit regelmäßigem oder unregelmäßigem Umlang ausgebildet ist, und daß der Innenumfang der Scheibe einen viereckigen oder unregelmäßigen Querschnitt hat.
3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Auflageflächen der Scheibe (14, 35, 53) Rauhigkeiten, Porenwel-  
ligkeiten oder andere Unebenheiten aufweisen.
4. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Auflageflächen der Scheiben (14, 35, 53) herausragende Spitzen (20) aufweisen.
5. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (45) Kanäle (46) aufweist, in die Knochenzement oder Knochenmaterial einbringbar ist.

6. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (11 bis 14, 21, 35, 45, 53) aus faserverstärktem Kunststoff besteht und im Wickelvorfahren oder ausaufgerollten Fasermatten hergestellt ist.

7. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (53) aus einem Strang (32, 33 bzw. 50) geschnitten ist.

8. Implantat nach Anspruch 7, dadurch gekennzeichnet, daß der Strang (32, 33 bzw. 50) aus unidirektionalen Fasern (32) und/oder Flechtlagen (33, 51) besteht.

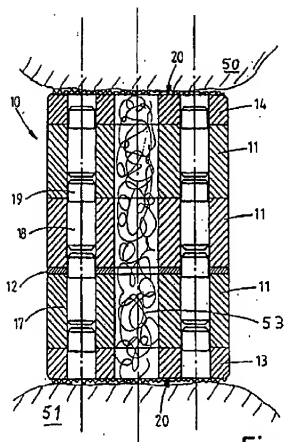


Fig. 1

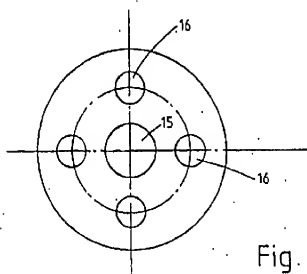


Fig. 2

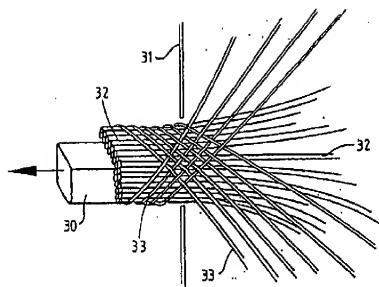


Fig. 5

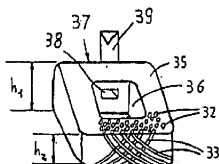


Fig. 6

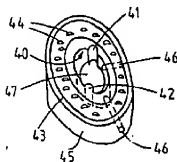


Fig. 7

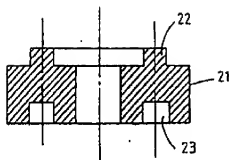


Fig. 3

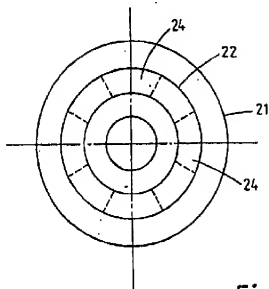


Fig. 4

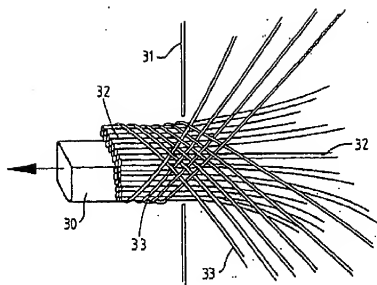


Fig. 5

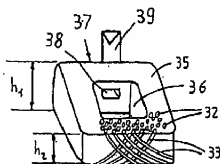


Fig. 6

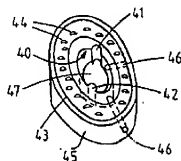


Fig. 7

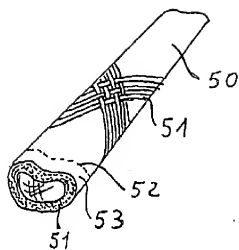


Fig. 8

## **EXHIBIT 33**



US005989289A

**United States Patent** [19][11] **Patent Number:** 5,989,289

Coates et al.

[45] **Date of Patent:** Nov. 23, 1999[54] **BONE GRAFTS**

## FOREIGN PATENT DOCUMENTS

[75] **Inventors:** Bradley J. Coates, Rossville; James Van Hoek, Cordova; Jeffrey Peyner, Aloka, all of Tenn.

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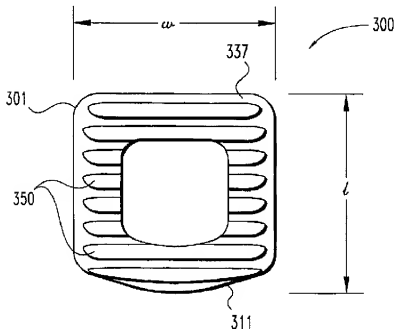
[73] **Assignee:** SDGI Holdings, Inc., Wilmington, Del.*Primary Examiner*—David J. Isabella[\*] **Notice:** This patent is subject to a terminal disclaimer.*Attorney, Agent, or Firm*—Woodard, Emhardt, Naughton, Moriarty & McNett[21] **Appl. No.:** 08/948,135[57] **ABSTRACT**[22] **Filed:** Oct. 9, 1997**Related U.S. Application Data**

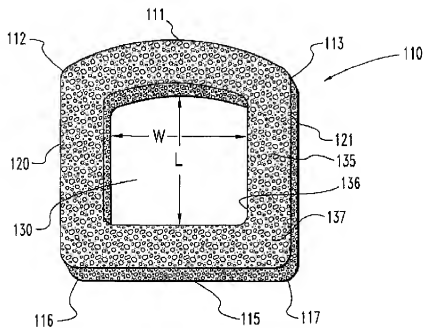
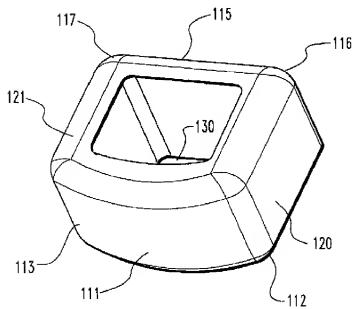
[63] Continuation of application No. 08/002,937, Jul. 30, 1997, abandoned, which is a continuation-in-part of application No. 08/740,031, Oct. 23, 1996, which is a continuation-in-part of application No. 08/603,676, Feb. 20, 1996, abandoned, which is a continuation-in-part of application No. 08/543,563, Oct. 16, 1995, abandoned, and a continuation-in-part of application No. 08/603,675, Feb. 20, 1996, abandoned, which is a continuation-in-part of application No. 08/543,563, Oct. 16, 1995, abandoned.

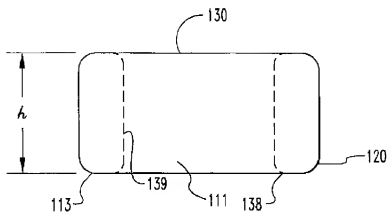
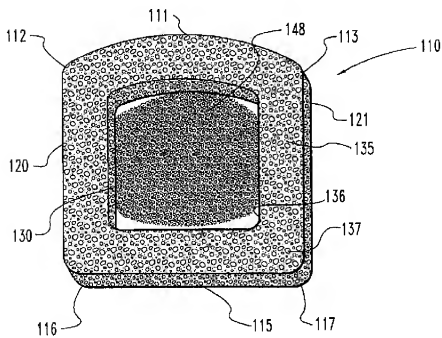
A spinal spacer 300 for engagement between vertebrae is provided which includes a body 301 formed of a bone composition. The body 301 includes a first end 311, an opposite second 315 end, a superior face 335 defining a superior vertebral engaging surface 337 and an inferior face 338 defining an inferior vertebral engaging surface 340. At least one of the vertebral engaging surfaces defines a set of migration resistance grooves 350. Each of the grooves 350 includes a first face 355 defining an angle of no more than about 90 degrees relative to the engaging surface 340 and a second opposing sloped face 360. The first and second faces 355, 360 define an arcuate pocket 370 therebetween for trapping vertebral bone to resist migration of the spacer 300. In one embodiment, the grooves 350 are arranged in series in that all of the second faces 360 slope in the same direction.

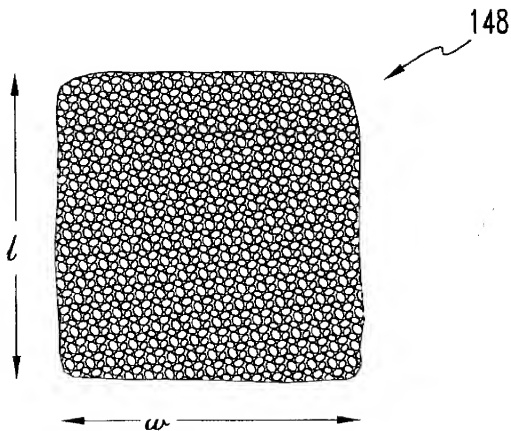
[51] **Int. Cl.** ..... A61F 2/44[52] **U.S. Cl.** ..... 623/17[58] **Field of Search** ..... 623/17, 18, 21; 606/61[56] **References Cited****U.S. PATENT DOCUMENTS**

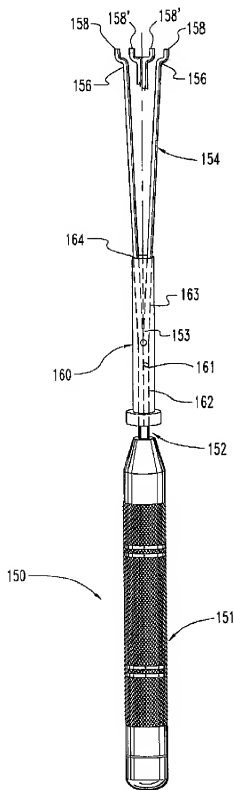
4,685,919 8/1987 Niwa et al. .... 623/21

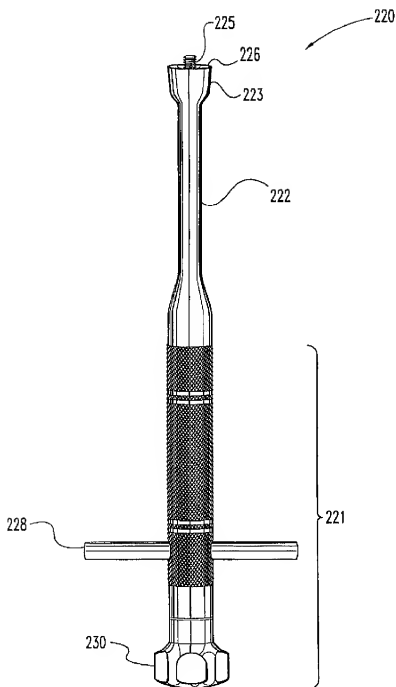
**24 Claims, 11 Drawing Sheets**

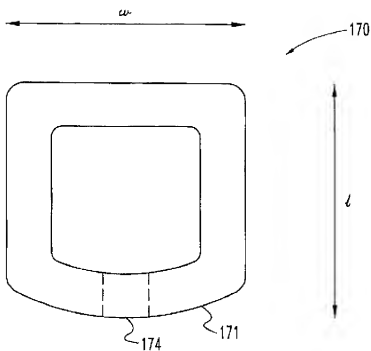
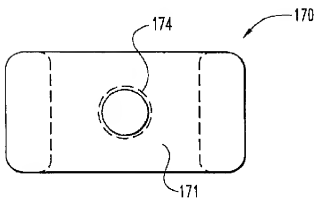
**Fig. 1****Fig. 2**

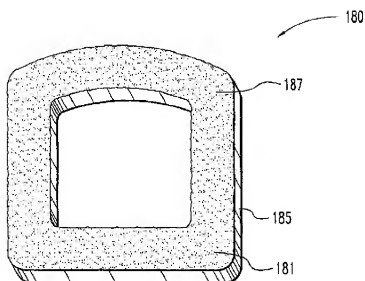
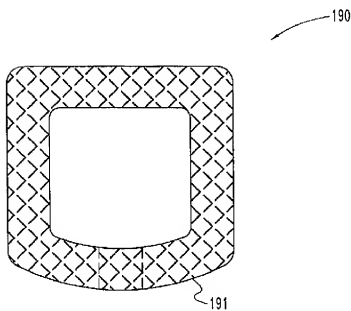
**Fig. 3****Fig. 4**

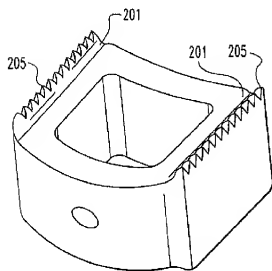
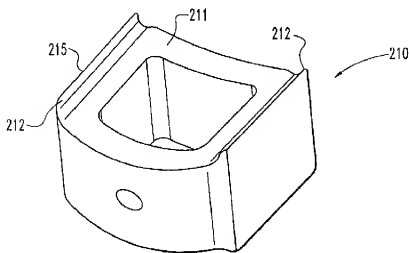
**Fig. 5**

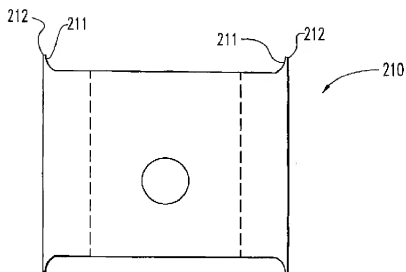
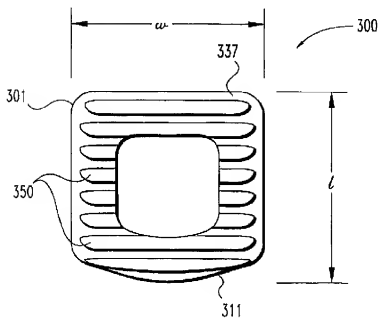
**Fig. 6**

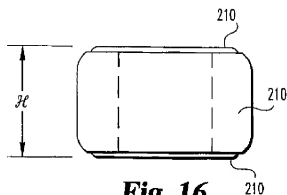
**Fig. 7**

**Fig. 8****Fig. 9**

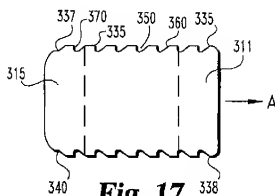
**Fig. 10****Fig. 11**

**Fig. 12****Fig. 13**

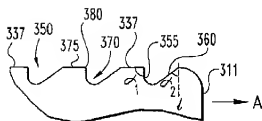
**Fig. 14****Fig. 15**



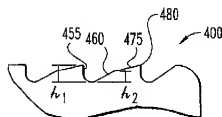
**Fig. 16**



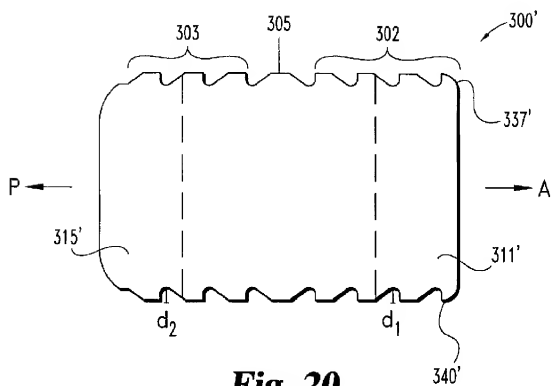
**Fig. 17**



**Fig. 18**



**Fig. 19**

**Fig. 20**

## BONE GRAFTS

This application is a continuation of Ser. No. 08/092,937, filed Jul. 30, 1997, now abandoned, which is a continuation-in-part application of Ser. No. 08/740,031, filed Oct. 23, 1996, pending, which is a continuation-in-part application of Ser. No. 08/603,676 filed Feb. 20, 1996, now abandoned, which is a continuation-in-part application of Ser. No. 08/543,563 filed Oct. 16, 1995, now abandoned; and Ser. No. 08/603,675, filed Feb. 20, 1996, now abandoned, which is a continuation-in-part application of Ser. No. 08/543,563 filed Oct. 16, 1995, now abandoned.

## FIELD OF THE INVENTION

The present invention relates to spacers, compositions, instruments and methods for arthrodesis. In specific applications of the invention the spacers include bone grafts having advantageous shapes and surface features.

## BACKGROUND OF THE INVENTION

Spinal fusion is indicated to provide stabilization of the spinal column for painful spinal motion and disorders such as structural deformity, traumatic instability, degenerative instability, and post-resection iatrogenic instability. Fusion, or arthrodesis, is achieved by the formation of an osseous bridge between adjacent motion segments. This can be accomplished within the disc space, anteriorly between contiguous vertebral bodies or posteriorly between consecutive transverse processes, laminae or other posterior aspects of the vertebrae.

An osseous bridge, or fusion mass, is biologically produced by the body upon skeletal injury. This normal bone healing response is used by surgeons to induce fusion across abnormal spinal segments by recreating spinal injury conditions along the fusion site and then allowing the bone to heal. A successful fusion requires the presence of osteogenic or osteoprogenitor cells, adequate blood supply, sufficient inflammatory response, and appropriate preparation of local bone. This biological environment is typically provided in a surgical setting by decontamination, or removal of the outer, cortical bone to expose the vascular, cancellous bone, and the deposition of an adequate quantity of high quality graft material.

A fusion or arthrodesis procedure is often performed to treat an anomaly involving an intervertebral disc. Intervertebral discs, located between the endplates of adjacent vertebrae, stabilize the spine, distribute forces between vertebrae and cushion vertebral bodies. A normal intervertebral disc includes a semi-gelatinous component, the nucleus pulposus, which is surrounded and confined by an outer, fibrous ring called the annulus fibrosus. In a healthy, undamaged spine, the annulus fibrosus prevents the nucleus pulposus from protruding outside the disc space.

Spinal discs may be displaced or damaged due to trauma, disease or aging. Disruption of the annulus fibrosus allows the nucleus pulposus to protrude into the vertebral canal, a condition commonly referred to as a herniated or ruptured disc. The extruded nucleus pulposus may press on the spinal nerve, which may result in nerve damage, pain, numbness, muscle weakness and paralysis. Intervertebral discs may also deteriorate due to the normal aging process or disease. As a disc dehydrates and hardens, the disc space height will be reduced leading to instability of the spine, decreased mobility and pain.

Sometimes the only relief from the symptoms of these conditions is a discectomy, or surgical removal of a portion

or all of an intervertebral disc followed by fusion of the adjacent vertebrae. The removal of the damaged or unhealthy disc will allow the disc space to collapse. Collapse of the disc space can cause instability of the spine, abnormal joint mechanics, premature development of arthritis or nerve damage, in addition to severe pain. Pain relief via discectomy and arthrodesis requires preservation of the disc space and eventual fusion of the affected motion segments.

Bone grafts are often used to fill the intervertebral space to prevent disc space collapse and promote fusion of the adjacent vertebrae across the disc space. In early techniques, bone material was simply disposed between the adjacent vertebrae, typically at the posterior aspect of the vertebrae, and the spinal column was stabilized by way of a plate or rod spanning the affected vertebrae. Once fusion occurred the hardware used to maintain the stability of the segment became superfluous and was a permanent foreign body. Moreover, the surgical procedures necessary to implant a rod or plate to stabilize the level during fusion were frequently lengthy and involved.

It was therefore determined that a more optimal solution to the stabilization of an excised disc space is to fuse the vertebrae between their respective end plates, preferably without the need for anterior or posterior plating. There have been an extensive number of attempts to develop an acceptable intra-discal implant that could be used to replace a damaged disc and maintain the stability of the disc interspace between the adjacent vertebrae, at least until complete arthrodesis is achieved. To be successful the implant must provide temporary support and allow bone ingrowth. Success of the discectomy and fusion procedure requires the development of a contiguous growth of bone to create a solid mass because the implant may not withstand the cyclic compressive spinal loads for the life of the patient.

Many attempts to restore the intervertebral disc space after removal of the disc have relied on metal devices. U.S. Pat. No. 4,878,915 to Brantigan teaches a solid metal plug. U.S. Pat. Nos. 5,044,104; 5,026,373 and 4,961,740 to Ray; 5,015,247 to Michelson and U.S. Pat. No. 4,820,305 to Harms et al., U.S. Pat. Nos. 5,147,402 to Bohler et al. and 5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.

Various bone grafts and bone graft substitutes have also been used to promote osteogenesis and to avoid the disadvantages of metal implants. Both allograft and autograft are biological materials which are replaced over time with the patient's own bone, via the process of creeping substitution. Over time a bone graft virtually disappears unlike a metal implant which persists long after its useful life. Stress shielding is avoided because bone grafts have a similar modulus of elasticity as the surrounding bone. Commonly used implant materials have stiffness values far in excess of both cortical and cancellous bone. Titanium alloy has a stiffness value of 114 Gpa and 316L stainless steel has a stiffness of 193 Gpa. Cortical bone, on the other hand, has a stiffness value of about 17 Gpa. Moreover, bone as an implant also allows excellent postoperative imaging because it does not cause scattering like metallic implants on CT or MRI imaging.

Various spacers have been constructed from bone or graft substitute materials to fill the intervertebral space after the

removal of the disc. For example, the Cloward dowel is a circular graft made by drilling an allogenic or autogenic plug from the ilium. Cloward dowels are bicortical, having porous cancellous bone between two cortical surfaces. Such dowels have relatively poor biomechanical properties, in particular a low compressive strength. Therefore, the Cloward dowel is not suitable as an intervertebral spacer without internal fixation due to the risk of collapsing prior to fusion under the intense cyclic loads of the spine.

Unfortunately, the use of bone grafts presents several disadvantages. Autograft is available in only limited quantities. The additional surgery also increases the risk of infection and blood loss and may reduce structural integrity at the donor site. Furthermore, some patients complain that the graft harvesting surgery causes more short-term and long-term pain than the fusion surgery.

Both allograft and autograft present additional difficulties. Graft alone may not provide the stability required to withstand spinal loads. Internal fixation can address this problem but presents its own disadvantages such as the need for more complex surgery as well as the disadvantages of metal fixation devices. Also, the surgeon is often required to repeatedly trim the graft material to obtain the correct size to fill and stabilize the disc space. This trial and error approach increases the length of time required for surgery. Furthermore, the graft material usually has a smooth surface which does not provide a good friction fit between the adjacent vertebrae. Migration and expulsion of the graft may cause neural and vascular injury, as well as collapse of the disc space. Even where such slippage does not occur, micromotion at the graft/fusion-site interface may disrupt the healing process that is required for fusion.

Several attempts have been made to develop a bone graft substitute which avoids the disadvantages of metal implants and bone grafts while capturing advantages of both. In each case, developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been extremely difficult or impossible.

A need has remained for fusion spacers which stimulate bone ingrowth and provide sufficient strength to support the vertebral column until the adjacent vertebrae are fused yet avoid the disadvantages of graft migration, stress shielding and the presence of a permanent foreign body.

### SUMMARY OF THE INVENTION

In accordance with one aspect of the invention, spinal spacers and compositions are provided for fusion of a motion segment. Spacers include a load bearing body sized for engagement within the space between adjacent vertebrae after discectomy to maintain the space. The body is formed of a bone composition and includes a first end defining a first surface, an opposite second end defining a second surface, a superior face defining a superior vertebral engaging surface and an inferior face defining an inferior vertebral engaging surface. The spacers include means for resisting migration. In one embodiment, the means include a set of migration resistant grooves defined in at least one of the vertebral engaging surfaces. Each of the grooves includes a first face defining an angle of no more than about 90° relative to the engaging surface and a second opposing sloped face. The first and second faces define a pocket therebetween for trapping vertebral bone. In another embodiment the set of grooves is defined in the first portion of the engaging surface and a second set of migration resistant grooves is defined in a second portion of the surface to resist migration in two directions.

One object of the invention is to provide spacers for engagement between vertebrae which resist migration of the implanted spacers, yet encourage bone ingrowth and avoid stress shielding. Another object of the invention is to provide a spacer which restores the intervertebral disc space and supports the vertebral column while promoting bone ingrowth.

One benefit of the spacers of the present invention is that they combine the advantages of bone grafts with the advantages of metals, without the corresponding disadvantages. An additional benefit is that the invention provides a stable scaffold for bone ingrowth before fusion occurs. Still another benefit of this invention is that it allows the use of bone grafts without the need for metal cages or internal fixation, due to the compressive strength of the spacer and the means for resisting migration. Other objects and further benefits of the present invention will become apparent to persons of ordinary skill in the art from the following written description and accompanying Figures.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a D-shaped spacer of this invention.

FIG. 2 is a front perspective view of the spacer of FIG. 1.

FIG. 3 is a front elevational view of the spacer depicted in FIG. 1.

FIG. 4 is a top perspective view of the spacer of FIG. 1 showing the chamber packed with a collagen sponge.

FIG. 5 is a top elevational view of a collagen sponge.

FIG. 6 is an implant insertion device.

FIG. 7 depicts a side elevational view of an implanting tool.

FIG. 8 is a D-spaced spacer of this invention having a tool engaging hole.

FIG. 9 is a front elevational view of the spacer FIG. 8.

FIG. 10 is a top elevational view of another embodiment of the spacer.

FIG. 11 is a top elevational view of another embodiment of the spacer.

FIG. 12 is a top perspective view of another embodiment of the spacers of this invention having teeth.

FIG. 13 is a top elevational view of another embodiment of the spacer having blades.

FIG. 14 is a front elevational view of the spacer of FIG. 13.

FIG. 15 is a top elevational view of a spacer having migration resistance grooves.

FIG. 16 is a front elevational view of the spacer of FIG. 15.

FIG. 17 is a side elevational view of the spacer of FIG. 15.

FIG. 18 is a side elevational detailed view of the surface of the spacer of FIG. 15.

FIG. 19 is a side elevational detailed view of the surface of another spacer of this invention.

FIG. 20 is a top elevational view of another embodiment of the spacer having two sets of migration resistance grooves.

### DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific

language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated spacers, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention provides spacers for engagement between vertebrae which are sized and configured to fill the space left after discectomy. The inventive spacers restore the height of the intervertebral disk space and provide immediate load bearing capability and support for the vertebral column without internal fixation. This invention eliminates the need for invasive autograft harvesting and trial and error trimming of graft material to fit the intra-distal space. The implants advantageously have an anatomically friendly shape and features which increase stability and decrease the risk of complications. In preferred embodiments, the spacers have the compressive strength of cortical bone with the advantage of incorporation of the spacer material without stress shielding. The migration resistance means prevents slippage, expulsion or micromotion. In this way, the spacers of this invention simulate bone ingrowth like a bone graft and provide sufficient strength to support the vertebral column but avoid the disadvantages of both bone graft and metal implants such as graft migration, stress shielding and the presence of a permanent foreign body.

The migration resistance means increase post-operative stability of the spacer by engaging the adjacent vertebral endplates and anchoring the spacer to prevent expulsion. Such surface features also stabilize the bone-spacer interface and reduce micromotion to facilitate incorporation and fusion. These features also provide increased surface area which facilitates the process of bone healing and creeping substitution for replacement of the donor bone material and fusion.

In a specific embodiment, spacers are provided for engagement between vertebrae as depicted in FIGS. 1-4. Spacers of this invention can be conveniently incorporated into current surgical procedures such as, the Smith-Robinson technique for cervical fusion (Smith, M.D., G.W. and R. A. Robinson, M.D., "The Treatment of Certain Cervical-Spine Disorders By Anterior Removal Of The Intervertebral Disc And Interbody Fusion", *J. Bone And Joint Surgery*, 40-A:607-624 (1958) and Cloward, M.D., R. B., "The Anterior Approach For Removal Of Ruptured Cervical Disks", in meeting of the Harvey Cushing Society, Washington, D.C., Apr. 22, 1958). In such procedures, the surgeon prepares the endplates of the adjacent vertebral bodies to accept a graft after the disc has been removed. The endplates are generally prepared to be parallel surfaces with a high speed burr. The surgeon then typically sculpts the graft to fit tightly between the bone surfaces so that the graft is held by compression between the vertebral bodies. The bone graft is intended to provide structural support and promote bone ingrowth to achieve a solid fusion of the affected joint. The spacers of this invention avoid the need for this graft sculpting as spacers of known size and dimensions are provided. This invention also avoids the need for a donor surgery because the osteoinductive properties of autograft are not required. The spacers can be combined with osteoinductive materials that make allograft osteoinductive. Therefore, the spacers of this invention speed the patient's recovery by reducing surgical time, avoiding a painful donor surgery and inducing quicker fusion.

The spacer 110 includes an anterior wall 111 having opposite ends 112, 113, a posterior wall 115 having opposite

ends 116, 117 and two lateral walls 120, 121. Each of the lateral walls 120, 121 is connected between the opposite ends 112, 113, 116, 117 of the anterior 111 and posterior 115 walls to define a chamber 130. The walls are each composed of a bone composition, preferably cortical bone. The walls also include the superior face 135 which defines a first opening 136 in communication with the chamber 130. The superior face 135 includes a first, superior friction or vertebral engaging surface 137. As shown in FIG. 3, the walls further include an opposite inferior face 138 defining a second opening 139 which is in communication with the chamber 130. The chamber 130 is preferably sized to receive an osteogenic composition to facilitate bone growth. The inferior face 138 includes a second, inferior friction or second vertebral engaging surface (not shown) which is similar to or identical to the first friction or vertebral engaging surface 137.

The spacers of the present invention are preferably combined with an osteogenic material, such as a bone morphogenic protein (BMP). This combination provides structural support and enhances bone growth into and incorporation of the graft, resulting in fusion quicker than with graft alone.

An osteogenic material can be applied to the spacers of this invention by packing the chamber 130 with an osteogenic material 148 as shown in FIG. 4, by impregnating the graft with a solution including an osteogenic composition or by both methods combined. The composition may be applied by the surgeon during surgery or the spacer may be supplied with the composition preapplied. In these cases, the osteogenic composition may be stabilized for transport and storage such as by freeze-drying. The stabilized composition can be rehydrated and/or reactivated with a sterile fluid such as saline or water or with body fluids applied before or after implantation. Any suitable osteogenic material or composition is contemplated, including autograft, allograft, xenograft, demineralized bone, synthetic and natural bone graft substitutes, such as bioceramics and polymers, and osteoinductive factors. The term osteogenic composition used here means virtually any material that promotes bone growth or healing including natural, synthetic and recombinant proteins, hormones and the like.

Autograft can be harvested from locations such as the iliac crest using drills, gouges, curettes and trephines and other tools and methods which are well known to surgeons in this field. Preferably, autograft is harvested from the iliac crest with a minimally invasive donor surgery. The graft may include osteocytes or other bone reamed away by the surgeon while preparing the end plates for the spacer.

Advantageously, where autograft is chosen as the osteogenic material, only a very small amount of bone material is needed to pack the chamber 130. The autograft itself is not required to provide structural support as this is provided by the spacer 110. The donor surgery for such a small amount of bone is less invasive and better tolerated by the patient. There is usually little need for muscle dissection in obtaining such small amounts of bone. The present invention therefore eliminates many of the disadvantages of autograft.

The osteogenic compositions used in this invention preferably comprise a therapeutically effective amount of a substantially pure bone inductive factor to stimulate osteoinduction such as a bone morphogenetic protein in a pharmaceutically acceptable carrier. The preferred osteoinductive factors are the recombinant human bone morphogenic proteins (rhBMPs) because they are available in unlimited supply and do not transmit infectious diseases. Most preferably, the bone morphogenetic protein is a rhBMP-2,

rhBMP-4 or heterodimers thereof. The concentration of rhBMP-2 is generally between about 0.4 mg/ml to about 1.5 mg/ml, preferably near 1.5 mg/ml. However, any bone morphogenetic protein is contemplated including bone morphogenetic proteins designated as BMP-1 through BMP-13. BMPs are available from Genetics Institute, Inc., Cambridge, Mass. and may also be prepared by one skilled in the art as described in U.S. Pat. Nos. 5,187,076 to Wozney et al.; 5,366,875 to Wozney et al.; 4,877,864 to Wang et al.; 5,108,922 to Wang et al.; 5,116,738 to Wang et al.; 5,013,649 to Wang et al.; 5,106,748 to Wozney et al.; and PCT Patent Nos. WO93/00432 to Wozney et al.; WO94/26893 to Celeste et al.; and WO94/26892 to Celeste et al. All osteoinductive factors are contemplated whether obtained as above or isolated from bone. Methods for isolating bone morphogenetic protein from bone are described in U.S. Pat. No. 4,294,753 to Urist and Urist et al., 81 PNAS 371, 1984.

The choice of carrier material for the osteogenic composition is based on biocompatibility, biodegradability, mechanical properties and interface properties as well as the structure of the load bearing member. The particular application of the compositions of the invention will define the appropriate formulation. Potential carriers include calcium sulphates, polyactic acids, polyacrylates, collagen, calcium phosphates, polymeric acrylic esters and demineralized bone. The carrier may be any suitable carrier capable of delivering the proteins. Most preferably, the carrier is capable of being eventually resorbed into the body. One preferred carrier is an absorbable collagen sponge marketed by Integra LifeSciences Corporation under the trade name Helistat® Absorbable Collagen Hemostatic Agent. Another preferred carrier is an open cell polylactic acid polymer (OPLA). Other potential matrices for the compositions may be biodegradable and chemically defined calcium sulphates, calcium phosphates such as tricalcium phosphate (TCP) and hydroxyapatite (HA) and including injectable bicalcium phosphates (BCP), and polyanhydrides. Other potential materials are biodegradable and biologically derived, such as bone or dermal collagen. Further matrices are comprised of pure proteins or extracellular matrix compounds. The osteoinductive material may also be an admixture of BMP and a polymeric acrylic ester carrier, such as polymethylmethacrylate.

For packing the chambers of the spacers of the present invention, the carriers are preferably provided as a sponge which can be compressed into the chamber or as strips or sheets which may be folded to conform to the chamber. Preferably, the carrier has a width and length which are each slightly greater than the width and length of the chamber. It may be preferable for the carrier to extend out of the openings of the chamber to facilitate contact of the osteogenic composition with the highly vascularized tissue surrounding the fusion site. When the carrier is provided in several strips sized to fit within the chamber, the strips can be placed one against another to fill the interior. As with the folded sheet, the strips can be arranged within the spacer in several orientations. Preferably, the osteogenic material, whether provided in a sponge, a single folded sheet or in several overlapping strips, has a length corresponding to the length and width of the chamber.

One preferred carrier is a biphasic calcium phosphate ceramic. Hydroxyapatite/tricalcium phosphate ceramics are preferred because of their desirable bioactive properties and degradation rates in vivo. The preferred ratio of hydroxyapatite to tricalcium phosphate is between about 0:100 and about 65:35. Any size or shape ceramic carrier which will fit into the chambers defined in the load bearing member are

contemplated. Ceramic blocks are commercially available from Sclafamer Danek Group, B. P. 4-62180 Rang-du-Fliers, France and Bioland, 132 Route d'Espagne, 31100 Toulouse, France. Of course, rectangular and other suitable shapes are contemplated. The osteoinductive factor is introduced into the carrier in any suitable manner. For example, the carrier may be soaked in a solution containing the factor.

In a preferred embodiment, an osteogenic composition is provided to the pores of the load bearing member. The bone growth inducing composition can be introduced into the pores in any suitable manner. For example, the composition may be injected into the pores of the graft. In other embodiments, the composition is dripped onto the graft or the graft is soaked in a solution containing an effective amount of the composition to stimulate osteoinduction. In either case the pores are exposed to the composition for a period of time sufficient to allow the liquid to thoroughly soak the graft. The osteogenic factor, preferably a BMP, may be provided in freeze-dried form and reconstituted in a pharmaceutically acceptable liquid or gel carrier such as sterile water, physiological saline or any other suitable carrier. The carrier may be any suitable medium capable of delivering the proteins to the spacer. Preferably the medium is supplemented with a buffer solution as is known in the art. In one specific embodiment of the invention, rhBMP-2 is suspended or admixed in a carrier, such as water, saline, liquid collagen or injectable BCP. The BMP solution can be dripped into the graft or the graft can be immersed in a suitable quantity of the liquid. In a most preferred embodiment, BMP is applied to the pores of the graft and then lyophilized or freeze-dried. The graft-BMP composition can then be frozen for storage and transport.

In one specific embodiment shown in FIGS. 4 and 5, the D-shaped spacer 110 includes a collagen sponge 148 having a width W and length L which are each slightly greater than the width W and length L of the chamber. In a preferred embodiment, the sponge 148 is soaked with freeze dried rhBMP-2 reconstituted in buffered physiological saline and then compressed into the chamber 130. The sponge 148 is held within the chamber 130 by the compressive forces provided by the sponge 148 against the walls 111, 115, 120, 121 of the spacer 110.

The spacers may be of any suitable shape, such as oval, rectangular and kidney-shaped. However, in one specific embodiment, the spacer is D-shaped. The anterior wall 111 as shown in FIGS. 1-4 has a convexly curved anterior surface 114. This anterior curvature is preferred to conform to the geometry of the adjacent vertebral bone and specifically to the harder cortical bone of the vertebrae. The D-shape of the spacer 110 also prevents projection of the anterior wall 111 outside the anterior aspect of the disc space, which can be particularly important for spacers implanted in the cervical spine.

The spacers are shaped advantageously for cervical arthrodesis. The flat posterior and lateral walls 115, 120 and 121, as shown in FIG. 1, can be easily incorporated into a Smith Robinson surgical fusion technique. After partial or total discectomy and distraction of the vertebral space, the surgeon prepares the end plates for the spacer 110 preferably to create flat posterior and lateral edges. The spacer 110 fits snugly with its flat surfaces against the posterior and lateral edges which prevents medial and lateral motion of the spacer 110 into vertebral arteries and nerves. This also advantageously reduces the time required for the surgery by eliminating the trial and error approach to achieving a good fit with bone grafts because the spacers can be provided in predetermined sizes.

Devices such as the spacer 110 can be inserted into the fusion site during an open or percutaneous surgery using an insertion device such as the one depicted in FIG. 6. The inserter 150 includes a handle 151 with knurlings or other suitable patterns to enhance manual gripping of the handle. A shaft 152 extends from the handle 151 and is generally divided into two portions: a solid portion 153 and a split jaw portion 154. The split jaw portion 154 is at the distal end of the shaft 152 opposite the handle 151. In the preferred embodiment, the split jaw portion 154 includes two jaws 156 each having an offset gripping surface 158 at their free ends. As depicted in FIG. 6 the split jaw portions 154 are movable from a fully opened position as represented by the fully separated position of the gripping surfaces 158. The split jaw portion 154 is closable to a fully closed position in which the two jaws 156 are in contact with one another. In the fully closed position, the gripping surfaces, identified as 158' in FIG. 6, are separated by a distance sufficiently close to grip a hollow spacer 110 therebetween. In particular, the closed gripping surfaces 158' contact the side surfaces of the two lateral walls 120, 121 of the spacer 110. In one preferred embodiment, the gripping surfaces 158 are roughened or knurled to enhance the grip on the spacer 110.

The inserter 150 further includes a sleeve 160 that is concentrically disposed around shaft 152. Preferably the sleeve 160 defines an inner bore 161 with a first portion 162 having a diameter slightly greater than the diameter of shaft 152. The internal bore 161 includes a flared portion 163 at its distal end 164. In the preferred embodiment, when the jaws 156 of the split jaw portion 154 are in their fully opened position, the jaws contact the flared portion 63 of the bore 161.

In the use of the inserter 150, the sleeve 160 is slid along the shaft 152, and more particularly along the opened jaws 156, to push the jaws together. As the jaws are pushed together, the gripping surfaces 158 engage and firmly grip a spacer 110 as described above. This inserter can then be extended percutaneously into the surgical site to implant a spacer 110 in the intra-discal space. Once the spacer is properly positioned, the sleeve 160 can be moved back toward the handle 151, so that the natural resilience of the two jaws 156 cause them to spread apart, thereby releasing the spacer 110. The inserter 150 can then be withdrawn from the surgical site with the jaws fully opened, or the sleeve can be advanced along the shaft once the gripping surfaces 158 have cleared the spacer 110. Other details of a similar device are disclosed in commonly assigned, pending U.S. application Ser. No. 08/697,784, IMPLANT INSERTION DEVICE. Metal spacers, insertion devices and methods relating to the same are disclosed in commonly assigned and co-pending applications: U.S. patent application Ser. No. 08/603,675, VERTEBRAL SPACER, U.S. patent application Ser. No. 08/603,676, INTERVERTEBRAL SPACER and U.S. patent application, Attorney Docket No. 97-59-PA/4002-1612.

Alternatively, the spacers of this invention may be provided with a tool engaging hole for insertion such as the tool depicted in FIG. 7. According to another specific embodiment depicted in FIGS. 8 and 9, the spacer 170 includes an anterior wall 171 defining a tool engaging hole 174. In a most preferred embodiment, the tool engaging hole 174 is threaded for receiving a threaded implanting tool such as depicted in FIG. 7. The inserter 220 includes a handle portion 221 with knurlings or other suitable patterns to enhance manual gripping of the handle. A shaft 222 extends from the handle 221. The distal end 223 of the shaft 222 includes a tip 225 which mates with the tool engaging hole

174. Preferably the tip 225 and tool engaging hole 174 have corresponding mating threads 226, 178. Where the tool engaging hole 174 is defined in a curved wall as shown in FIG. 8, the distal end 223 of the shaft 222 preferably includes a curved portion 224 that conforms to the curved anterior surface of the spacer. The inserter 220 also preferably includes a T-handle 228 for spacer control and positioning. Preferably the inserter 120 includes means for rotating the threaded tip 225. In FIG. 7, the knob 230 is engaged to the tip 225 via an inner shaft extending through an internal bore (not shown) in the handle 221 and shaft 222. The tip 225 is preferably at the end of the inner shaft with the inner shaft rotatably mounted within the handle 221 and shaft 222.

In the use of the inserter 220, a spacer 170 is engaged to the threaded tip 225 with the curved portion 224 flush with the anterior wall 171. The inserter and spacer can then be extended percutaneously into the surgical site to implant the spacer in the intra-discal space. Once the spacer 170 is properly positioned, the knob 230 can be turned to rotate the threaded tip 225 and disengage the tip from the hole 174 of the spacer 110. The inserter 220 can then be withdrawn from the surgical site leaving the spacer 170 in place.

In preferred embodiments, the spacers are provided with migration resistance means. The engaging surfaces of the spacers can be machined to facilitate engagement with the endplates of the vertebrae and prevent slippage of the spacer as is sometimes seen with smooth grafts prepared at the time of surgery. Referring now to FIG. 10, the spacer 180 may be provided with a roughened surface 181 on one of the engaging surfaces 187 of one or both of the superior face 188 or inferior face (not shown). The roughened surface 191 of the spacer 190 may include a waffle or other suitable pattern as depicted in FIG. 11. In one preferred embodiment shown in FIG. 12, the engaging surfaces 201 include teeth 205 which provide biting engagement with the endplates of the vertebrae. In another embodiment (FIGS. 13 and 14), the spacer 210 includes engaging surfaces 211 machined to include one or more blades 212. Each blade includes a cutting edge 213 configured to pierce a vertebral end-plate. The blade 212 can be driven into the bone surface to increase the initial stability of the spacer.

In a preferred embodiment depicted in FIGS. 15-18, the migration resistance means includes a set of expulsion resistance grooves defined in the body 301 of the spacer 300. In this spacer, the superior and inferior vertebral engaging surfaces 337 and 340 define a set of migration resistance grooves 350. As shown more clearly in FIG. 18 each of the grooves 350 includes a first face 355. The first face 355 defines an angle  $\alpha_1$  no more than about 90° relative to the engaging surface 337. Preferably, the angle  $\alpha_1$  is 90°. In other words, the first face 355 is preferably perpendicular to the engaging surface 337. Each groove 350 also includes a second, opposing and sloped face 360. The sloped face 360 preferably forms an angle  $\alpha_2$  relative to a line 1 which is parallel to the first face 355. The first face 355 and second face 360 define a pocket 370 therebetween for trapping vertebral bone.

Preferably each of the grooves 350 of the set 302 are arranged in series in that each second face 360 slants in the same direction as the others. In the embodiment shown in FIGS. 15-18, each of the grooves 350 slants away from the posterior or second end 315 and towards the first end or anterior wall 311 of the body 301. In this embodiment the engaging surface 337 defines a peak 375 between each of the grooves 350. The peak 375 preferably defines a flattened surface. The vertebral engaging surface 337 may be pro-

vided with a cutting edge 380 between the first face 355 and the engaging surface 375.

Referring now to the spacer 400 of FIG. 19, the exact configuration of the grooves may vary. For example, the first face 355 may have a first height  $h_1$  between the pocket 470 and the engaging surface 437 which is taller than a second height  $h_2$  of the second face 450. In this embodiment, the peak 475 is sloped toward the cutting edge 480.

In preferred embodiments, the pocket 370 is substantially arcuate or circular in shape. The pocket is configured for collecting and trapping vertebral bone if the spacer migrates after it is implanted. For example, the embodiment depicted in FIGS. 15-18 has grooves that resist migration in the direction of the arrow A. If the spacer is implanted with the first or anterior end 311 to the anterior of the patient using an anterior approach, the anterior tissues will be weakened and migration will most likely occur in the anatomically anterior direction. The spacer can be configured for implantation with the grooves facing in a direction that resists that anterior migration. If a force urges the spacer 300 in the anterior direction, the edge 380 of the peak 375 will dig into the vertebral bone and bone will collect in the pocket 370.

The spacers of this invention may also be provided with means that resist migration in two directions. Referring now to FIG. 20, the spacer 300 includes a first set of grooves 301 which resist migration in the direction of arrow A and a second set of grooves 302 which resist migration in the direction of arrow P. The two sets of grooves 302 and 303 meet at a flattened bridge member 305. The first set of grooves 302 slants towards the first end 311' and resists migration in the direction of the arrow A. The second set of grooves 303 slants towards the second end 315' and resists migration in the direction of the arrow P. In this way the grooves resist micromotion, migration and expulsion.

As shown in FIG. 20, the depth of the grooves may vary between the two sets 302 and 303. The grooves of the two sets 302 and 303 have a depth  $d_1$ ,  $d_2$  below the vertebral engaging surface 337 and 340'. The grooves of the first set 302 or the second set 303 may be deeper than the other as needed for the particular application.

The spacers of this invention are preferably formed of a bone composition or material. The bone may be autograft, allograft, xenograft or any of the above prepared in a variety of ways. Cortical bone is preferred for its compressive strength. In one embodiment, the spacers are obtained as a cross sectional slice of a shaft of a long bone. For example, various shaped spacers may be obtained by machining a cortical ring into the desired configuration. The exterior surfaces of the walls can be formed by machining the ring to a D-shape. Material from the medullary canal of the ring can be removed to form a chamber. Surface features and migration resistance means can be defined into the surface of the spacers using conventional machining methods and a standard milling machine which have been adapted to bone. Various methods and procedures are known for treating and processing bone to provide bone materials and compositions. These methods and procedures can be applied to the present invention as long as the resulting bone material provides a sufficient compressive strength for the intended application.

Spacers of the present invention can be made to any suitable size or shape which is suitable for the intended application. Referring now to FIGS. 15 and 16, the spacer has a width W of preferably 11 to 14 millimeters, a length L of preferably between about 11 and 14 millimeters and a height H of about 7 millimeters. The height H is the distance

between the highest peak 375 on the superior vertebral engaging surface 337 and the highest peak 375 on the inferior vertebral engaging surface 340.

Advantageously, the intervertebral spacers of the present invention may not require internal fixation. The spacers are contained by the compressive forces of the surrounding ligaments and muscles, and the disc annulus if it has not been completely removed. Temporary external immobilization and support of the instrumented and adjacent vertebral levels, with a cervical collar, lumbar brace or the like, is generally recommended until adequate fusion is achieved.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed:

1. A spinal spacer for engagement between vertebrae, comprising:
  - a body formed of a bone composition and including a first end, an opposite second end, a superior face defining a superior vertebral engaging surface and an inferior face defining an inferior vertebral engaging surface; and
  - at least one of said vertebral engaging surfaces defining a first set of migration resistance grooves, each of said grooves including a first face defining an angle of no more than about 90 degrees relative to said one of said engaging surfaces and a second opposing sloped face, said first and second faces defining a substantially arcuate pocket therebetween for trapping vertebral bone.
2. The spacer of claim 1 wherein said grooves of said first set are arranged in series.
3. The spacer of claim 2 wherein each of said sloped faces is sloped toward said first end.
4. The spacer of claim 1 wherein said at least one of said vertebral engaging surfaces defines a peak between each of said grooves, said peak defining a flattened surface.
5. The spacer of claim 3 further comprising a second set of migration resistance grooves defined in series in at least one of said vertebral engaging surfaces, each of said grooves of said second set including a first face defining an angle of no more than about 90 degrees relative to said one of said engaging surfaces and a second opposing sloped face, said first and second faces of each of said grooves of said second set defining a pocket therebetween for trapping vertebral bone, each of said sloped faces of said second set sloping towards said second end.
6. The spacer of claim 5 wherein each of said grooves has a depth below said at least one of said vertebral engaging surfaces and said grooves of said first set are deeper than said grooves of said second set.
7. The spacer of claim 5 wherein each of said grooves has a depth below said at least one of said vertebral engaging surfaces and said grooves of said second set are deeper than said grooves of said first set.
8. The spacer of claim 1 wherein the pocket defined by said first and second faces is circularly rounded.
9. The spacer of claim 1 wherein said first face is perpendicular to said at least one of said vertebral engaging surfaces.
10. The spacer of claim 1 further comprising a cutting edge between said first face and said at least one of said vertebral engaging surfaces.
11. The spacer of claim 4 wherein said first face said pocket has a first height which is taller than a second height of said second face of said pocket, and said peak is sloped.

12. The spacer of claim 1 wherein said superior face defines a first opening and said inferior face defines a second opening, each of said openings in communication with a chamber formed through said body.

13. The spacer of claim 12 wherein said first end defines a convexly curved surface.

14. The spacer of claim 13 wherein said second end is flat.

15. A hollow spinal spacer for engagement between vertebrae, comprising:

a body formed of a bone composition and including an anterior wall with opposite ends and defining a convexly curved anterior surface, an opposite posterior wall having opposite ends and defining a flat posterior surface, two lateral walls, each integrally connected between said opposite ends of said anterior and posterior walls to define a chamber, said walls further defining a superior vertebral engaging surface defining a first opening, said first opening in communication with said chamber, and an inferior vertebral engaging surface defining a second opening, said second opening in communication with said chamber; and

at least one of said vertebral engaging faces defining a set of migration resistance grooves, each of said grooves including a first face defining an angle of no more than about 90 degrees relative to said one of said engaging surfaces and a second opposing sloped face, said first and second faces defining a substantially arcuate pocket therebetween for trapping vertebral bone, said grooves in series with said sloped faces sloping towards said anterior wall.

16. A spinal spacer for engagement between vertebrae, comprising:

a body formed of a bone composition and including a first end, an opposite second end, a superior face defining a superior vertebral engaging surface and an inferior face defining an inferior vertebral engaging surface; and

at least one of said vertebral engaging surfaces defining a first set of migration resistance grooves, each of said grooves including a first face defining an angle of no more than about 90 degrees relative to said one of said engaging surfaces and a second opposing sloped face, said first and second faces defining a pocket therebetween for trapping vertebral bone, said one of said

engaging surfaces defining a peak between each of said grooves, said peak defining a flattened surface.

17. The spacer of claim 16 further comprising a cutting edge between said first face and said at least one of said vertebral engaging surfaces.

18. The spacer of claim 16 wherein said first face at said pocket has a first height which is taller than a second height of said second face at said pocket, and said peak is sloped.

19. The spacer of claim 16 wherein said first face is perpendicular to said at least one of said vertebral engaging surfaces.

20. A spinal spacer for engagement between vertebrae, comprising:

a body formed of a bone composition and including a first end, an opposite second end, a superior face defining a superior vertebral engaging surface and an inferior face defining an inferior vertebral engaging surface; and

at least one of said vertebral engaging surfaces defining a first set of migration resistance grooves, said at least one of said vertebral engaging surfaces defining a second set of migration resistance grooves, each of said grooves including a first face defining an angle of no more than about 90 degrees relative to said one of said engaging surfaces and a second opposing sloped face, said first and second faces defining a pocket therebetween for trapping vertebral bone, each of said sloped faces of said grooves of said first set sloping toward said first end, each of said sloped faces of said grooves of said second set sloping toward said second end.

21. The spacer of claim 20 wherein each of said grooves has a depth below said at least one of said vertebral engaging surfaces and said grooves of said first set are deeper than said grooves of said second set.

22. The spacer of claim 20 wherein each of said grooves has a depth below said at least one of said vertebral engaging surfaces and said grooves of said second set are deeper than said grooves of said first set.

23. The spacer of claim 20 wherein said at least one of said vertebral engaging surfaces defines a peak between each of said grooves, said peak defining a flattened surface.

24. The spacer of claim 23 wherein said first face at said pocket has a first height which is taller than a second height of said second face at said pocket, and said peak is sloped.

\* \* \* \* \*

UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION

PATENT NO : 5,989,289

DATED : November 23, 1999

INVENTOR(S) : Bradley J. Coates et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, item [63] the "Related U.S. Application Data" section, please delete the current text and replace it with the following:

-- Continuation of application No. 08/902,937, Jul. 30, 1997, abandoned, which is a continuation-in-part of application No. 08/740,031, Oct. 23, 1996; and of application No. 08/603,876, Feb. 20, 1996, abandoned, which is a continuation-in-part of application No. 08/543,563, Oct. 16, 1995, abandoned; and of application No. 08/603,675, Feb. 20, 1996, abandoned, which is a continuation-in-part of application No. 08/543,563, Oct. 16, 1995, abandoned. --

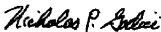
In col. 1, line 6, please delete ", which is a continuation-in-part application of" and insert in lieu thereof -- ; and of --.

In col. 1, line 9, please insert -- of -- in between "and" and "Ser.".

Signed and Sealed this

Twenty-seventh Day of March, 2001

Attest:



NICHOLAS P. GODICI

Attesting Officer

Acting Director of the United States Patent and Trademark Office

## RELATED PROCEEDINGS APPENDIX

NONE